



2008

Predicting Probability: Regulating the Future of Preimplantation Genetic Screening

Jaime King

Follow this and additional works at: <https://digitalcommons.law.yale.edu/yjhple>



Part of the [Health Law and Policy Commons](#), and the [Legal Ethics and Professional Responsibility Commons](#)

Recommended Citation

Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL'Y L. & ETHICS (2008).

Available at: <https://digitalcommons.law.yale.edu/yjhple/vol8/iss2/2>

This Article is brought to you for free and open access by Yale Law School Legal Scholarship Repository. It has been accepted for inclusion in Yale Journal of Health Policy, Law, and Ethics by an authorized editor of Yale Law School Legal Scholarship Repository. For more information, please contact julian.aiken@yale.edu.

Predicting Probability: Regulating the Future of Preimplantation Genetic Screening

Jaime King*

INTRODUCTION	285
I. PREIMPLANTATION GENETIC DIAGNOSIS AND SCREENING	290
A. CURRENT PGS USE	291
1. CHROMOSOMAL ANALYSIS	292
2. GENETIC ANALYSIS	295
B. LIMITATIONS ON CURRENT PGS USE	296
C. FUTURE CAPABILITIES OF PGS	298
II. IS PGS OVERSIGHT NECESSARY?	301
A. THE AUTHORITY OF SOCIETY OVER THE INDIVIDUAL	301
B. RISKS ASSOCIATED WITH PGS	303
1. RISKS TO OFFSPRING BORN VIA PGS	303
2. RISKS TO THE PROSPECTIVE PARENTS	308
3. RISKS TO SOCIETY	312
C. WHY HAS THE UNITED STATES NOT REGULATED PGS?	321
III. WHO SHOULD OVERSEE PGS?	323
A. PROFESSIONAL SOCIETIES	324
B. STATE AND FEDERAL GOVERNMENTS	326
1. STATE GOVERNMENT	329
2. FEDERAL GOVERNMENT	331
IV. HOW SHOULD THE UNITED STATES OVERSEE THE USE OF PGS?	338
A. FACTORS TO CONSIDER	339
1. PROTECTING INDIVIDUAL HEALTH AND WELL-BEING	339
2. PROTECTING SOCIETY	340

* J.D., Ph.D., Associate Professor of Law, University of California, Hastings College of the Law. The author would like to thank Hank Greely, Elizabeth Bartholet, Norman Daniels, Amitai Aviram, Andrew Bonnes, James King, Ben Moulton, Emily Murphy, Barry Staples, and Kristen Underhill for their helpful comments on earlier versions of this draft.

YALE JOURNAL OF HEALTH POLICY, LAW, AND ETHICS

VIII:2 (2008)

3. PROTECTING REPRODUCTIVE AUTONOMY	341
4. PRACTITIONERS' INTERESTS	342
B. POLICY DEVELOPMENT.....	343
1. ALIGNING SIMILAR INTERESTS	343
2. BALANCING CONFLICTING INTERESTS.....	346
C. ASSISTED REPRODUCTIVE TECHNOLOGY AUTHORITY.....	354
1. PROCEDURAL REGULATIONS	354
2. SUBSTANTIVE REGULATIONS.....	356
CONCLUSION	357

INTRODUCTION

At the intersection of two rapidly developing areas of biotechnology, a revolution is about to take place. Although this revolution involves reproduction, it will not be sexual. A medical procedure, known as preimplantation genetic diagnosis (PGD), combines genetic testing and assisted reproductive technology (ART) to enable parents to screen their potential children before implantation for genetic or chromosomal characteristics. The technology has been a godsend to couples with family histories of genetic disorders and chromosomal mutations causing infertility. However, expanding its use to permit prospective parents to select embryos based on a wide array of genetic characteristics presents substantial risks to individuals involved in the procedure and to society as a whole.

Although PGD use has remained extremely limited due to technological constraints, expense, and moderate success rates, recent advances in genetic testing procedures will remove many of these obstacles and significantly increase the benefits of its use. Better tests, providing better information, will expand the use of this technology from embryos known to be at risk for serious disease – preimplantation genetic *diagnosis* – to the testing of all or almost all in vitro embryos for multiple genetic characteristics – preimplantation genetic *screening* (PGS).¹

Future couples might select their potential children based on knowledge of their genetic susceptibility to serious diseases, like breast cancer² and Alzheimer's disease;³ their propensity for cardiac arrhythmia;⁴ the probability that they will develop more common diseases, like diabetes;⁵ the probability that they will have childhood asthma;⁶ their sex;⁷ their likely body-mass index and

1. Throughout the paper, preimplantation genetic diagnosis (PGD) will refer to genetic and chromosomal screening for diseases, and preimplantation genetic screening (PGS) will refer to genetic and chromosomal screening for all other conditions. In addition, PGS will be used to encompass both ideas at once.

2. See Rosalind A. Eeles, *Future Possibilities in the Prevention of Breast Cancer: Intervention Strategies in BRCA1 and BRCA2 Mutation Carriers*, 2 BREAST CANCER RES. 283 (2000).

3. See Charles R. Harrington et al., *Influence of Apolipoprotein E Genotype on Senile Dementia of the Alzheimer and Lewy Body Types: Significance for Etiological Theories of Alzheimer's Disease*, 145 AM. J. PATHOLOGY 1472 (1994).

4. See Daniel J. Gudbjartsson et al., *Variants Conferring Risk of Atrial Fibrillation on Chromosome 4q25*, 448 NATURE 353 (2007).

5. See Jose C. Florez et al., *TCF7L2 Polymorphisms and Progression to Diabetes in the Diabetes Prevention Program*, 355 NEW ENG. J. MED. 241 (2006).

6. See Miriam F. Moffat et al., *Genetic Variants Regulating ORMDL3 Expression Contribute to the Risk of Childhood Asthma*, 448 NATURE 470 (2007).

weight;⁸ their hair, eye, and skin color;⁹ their propensity for aggression;¹⁰ and their likely height.¹¹ As our knowledge of genetics expands, geneticists will be able to test embryos for the presence of gene variants, known as alleles,¹² associated with a range of conditions through the use of a DNA microarray, a testing device that can screen for thousands of alleles at one time. Combining these genetic advances with ART procedures will permit parents to select embryos based upon their potential future traits.¹³

While scientists and consumers pursue the promise of PGS, we must also acknowledge the potential harms associated with its widespread adoption. Recent studies suggest that while PGS has great potential, its benefits may not always outweigh its risks. A number of variables contribute to the risks associated with PGS. Assisted reproduction procedures performed as part of PGS, such as in vitro fertilization (IVF),¹⁴ intracytoplasmic sperm injection (ICSI),¹⁵ and embryo

7. See Medline Plus, Genetics, <http://www.nlm.nih.gov/medlineplus/ency/article/002048.htm> (last visited Apr. 18, 2008).

8. See Angelo Scuteri et al., *Genome-Wide Association Scan Shows Genetic Variants in the FTO Gene Are Associated with Obesity-Related Traits*, 3 PLOS GENETICS 1200 (2007), <http://www.plosgenetics.org/article/info%3Adoi%2F10.1371%2Fjournal.pgen.0030115> (follow link to PDF version).

9. See Maarten T. Bastiaens et al., *Melanocortin-1 Receptor Gene Variants Determine the Risk of Nonmelanoma Skin Cancer Independently of Fair Skin and Red Hair*, 68 AM. J. HUM. GENETICS 884 (2001) (finding that the MC1R gene is associated with red hair and fair skin in individuals of European descent); David L. Duffy et al., *A Three-Single-Nucleotide Polymorphism Haplotype in Intron 1 of OCA2 Explains Most Human Eye-Color Variation*, 80 AM. J. HUM. GENETICS 241 (2007).

10. See Kevin M. Beaver et al., *A Gene x Gene Interaction between DRD2 and DRD4 Is Associated with Conduct Disorder and Antisocial Behavior in Males*, 3 BEHAV. & BRAIN FUNCTIONS 30 (2007); Giovanni Frazzetto et al., *Early Trauma and Increased Risk for Physical Aggression During Adulthood: The Moderating Role of MAOA Genotype*, 2 PLOS ONE 1 (2007), <http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0000486> (follow link to PDF version); Essi Viding & Uta Frith, *Genes for Susceptibility to Violence Lurk in the Brain*, 103 PROC. NAT'L ACAD. SCI. 6085 (2006).

11. See Jianfeng Xu et al., *Major Recessive Gene(s) with Considerable Residual Polygenic Effect Regulating Adult Height: Confirmation of Genomewide Scan Results for Chromosomes 6, 9, and 12*, 71 AM. J. HUM. GENETICS 646 (2002).

12. Alleles are different variations of a gene. If only one gene controlled eye color, alleles would exist for blue, green, brown, and hazel eyes.

13. A number of companies are working on incorporating the DNA microarray and other high throughput testing devices into ART procedures, and these developments are rapidly approaching commercialization. See, e.g., Gene Security Network, <http://www.genesecurity.net/services.html> (last visited Mar. 30, 2008) (stating that its high throughput technology will offer parents information on all twenty-three chromosome pairs and multiple disease-linked genetic loci in 2008).

14. In vitro fertilization is a process through which eggs are removed from a woman's ovaries

PREDICTING PROBABILITY

biopsy,¹⁶ are associated with increased risks to the embryo, the mother, and the future child. Uncertainties inherent in the genetic testing process, such as inaccurate genetic tests,¹⁷ embryo mosaicism,¹⁸ and low gene penetrance,¹⁹ have

and fertilized with sperm in a Petri dish. Embryos are cultured in the dish for two to five days and then transferred to the uterus for implantation. See IVF-Infertility.com, Fertilization (Fertilisation), <http://www.ivf-infertility.com/ivf/standard/procedure/fertilization.php> (last visited Apr. 18, 2008); see also Jane Halliday, *Outcomes of IVF Conceptions: Are They Different?*, 21 BEST PRAC. & RES. CLINICAL OBSTETRICS & GYNAECOLOGY 67 (2007) (finding that perinatal outcomes such as preterm delivery, low birth weight and some birth defects occurred with increased frequency in single-child (singleton) IVF births); Dorte Hvidtjørn et al., *Cerebral Palsy Among Children Born After In Vitro Fertilization: The Role of Preterm Delivery - A Population-Based, Cohort Study*, 118 PEDIATRICS 475 (2006) (finding that IVF procedures that result in preterm deliveries posed an increased risk of cerebral palsy); Reija Klemetti et al., *Health of Children Born as a Result of In Vitro Fertilization*, 118 PEDIATRICS 1819 (2006) (finding that singleton IVF babies had higher incidences of perinatal problems, congenital malformations and problems of the genitourinary system than naturally conceived children; interestingly, the study also revealed a slight decrease in respiratory disease in children born via IVF).

15. ICSI, a procedure in which a single sperm is injected into the egg through the use of a micropipette, is commonly used in IVF and PGS procedures to ease fertilization when there are abnormalities in the function, number or quality of the sperm. See Am. Soc’y for Reprod. Med., Patient’s Fact Sheet: Intracytoplasm Sperm Injection (ICSI) (2001), available at <http://www.asrm.org/Patients/FactSheets/ICSI-Fact.pdf>; see also M. Bonduelle et al., *A Multi-Centre Cohort Study of the Physical Health of 5-Year-Old Children Conceived After Intracytoplasmic Sperm Injection, In Vitro Fertilization and Natural Conception*, 20 HUM. REPROD. 413, 416 (2005) (finding that 4.2% of children born via ICSI have a major congenital malformation, which is 2.77 times the rate of children naturally conceived; this result remained statistically significant when controlled for age, country, maternal age, education level, social class, maternal smoking habits, drinking, and number of previous pregnancies).

16. Embryo biopsy is the procedure in which the clinician removes one to two cells from an eight-cell embryo for genetic testing. See Sebastiaan Mastenbroek et al., *In Vitro Fertilization with Preimplantation Genetic Screening*, 357 NEW ENGL. J. MED. 9 (2007) (suggesting that the decrease from the live birthrate associated with IVF procedures alone (37%) to the live birthrate associated with PGS procedures (25%) might result from the embryo biopsy).

17. SUSANNAH BARUCH ET AL., GENETICS & PUB. POLICY CTR., PREIMPLANTATION GENETIC DIAGNOSIS: A DISCUSSION OF CHALLENGES, CONCERNS, AND PRELIMINARY POLICY OPTIONS RELATED TO THE GENETIC TESTING OF HUMAN EMBRYOS 5-6 (2004), available at <http://www.dnapolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf>.

18. Mosaic embryos contain certain cells with chromosomal and genetic structures that differ from those in the rest of the embryo. See Medline Plus, Mosaicism, <http://www.nlm.nih.gov/medlineplus/ency/article/001317.htm> (last visited Mar. 15, 2008). If tests are performed on these cells, they will provide an inaccurate depiction of the overall embryo.

19. Gene penetrance refers to the likelihood that the presence of a gene will result in the specific physical characteristic or phenotype associated with the gene. Some genes have one hundred percent penetrance, such that presence of the gene indicates that the resulting individual

also lead to embryo misdiagnosis, rendering the procedure ineffective. More broadly, widespread use of the technique can harm not only the individuals involved in it, but also society in general by increasing discrimination, stigmatization, and health disparities. The potential for individual and social harm resulting from these risks grows in proportion to the use and number of genetic tests available for PGS.

Now is the time for the United States to consider the potential impacts of PGS, and decide what role, if any, the federal government should play in overseeing its use. Over the past few years, a number of scholars have called for regulation of ART procedures in the United States.²⁰ This Article offers further evidence in support of more general ART regulation by examining the risks and benefits associated with recent advances in reproductive genetic testing and PGS.

In developing an appropriate response to recent advances in assisted reproductive technology and genetic testing, the United States should address three critical questions: 1) Does PGS need oversight?; if so, 2) What entities can best regulate PGS?; and 3) How should PGS be regulated?

After briefly describing the technologies involved, this Article will consider

will definitely have the disorder or characteristic. Other genes have lower penetrance, indicating that only some individuals with the gene will have the disorder or condition. Human Genome Project, Evaluating Gene Tests: Some Considerations, http://www.ornl.gov/sci/techresources/Human_Genome/resource/testeval.shtml (last visited Mar. 15, 2008).

20. See, e.g., FRANCIS FUKUYAMA & FRANCO FURGER, *BEYOND BIOETHICS: A PROPOSAL FOR MODERNIZING THE REGULATION OF HUMAN BIOTECHNOLOGIES* 293-300 (2006); June Carbone & Paige Gottheim, *Markets, Subsidies, Regulation, and Trust: Building Ethical Understandings into the Market for Fertility Services*, 9 J. GENDER, RACE & JUST. 509 (2006); Alexander N. Hecht, *The Wild Wild West: Inadequate Regulation of Assisted Reproductive Technology*, 1 HOUS. J. HEALTH L. & POL'Y 227 (2001); Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past—Present, and Future?*, 36 CONN. L. REV. 125 (2003) [hereinafter Malinowski, *Choosing*]; Michael J. Malinowski, *A Law-Policy Proposal To Know Where Babies Come from During the Reproduction Revolution*, 9 J. GENDER, RACE & JUST. 549 (2006) [hereinafter Malinowski, *A Law-Policy Proposal*]; Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603 (2003); Vicki G. Norton, *Unnatural Selection: Nontherapeutic Preimplantation Genetic Screening and Proposed Regulation*, 41 UCLA L. REV. 1581 (1994); Eric Parens & Lori P. Knowles, *Reprogenetics and Public Policy: Reflections and Recommendations*, 33 HASTINGS CENTER REP. S18-21 (2003); Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Can the Law Protect Them from Harm?*, 2004 UTAH L. REV. 57 (2004); Lindsey A. Vacco, *Preimplantation Genetic Diagnosis: From Preventing Genetic Disease to Customizing Children. Can the Technology Be Regulated Based on the Parents' Intent?*, 49 ST. LOUIS L.J. 1181 (2005); Aaron R. Fahrenkrog, Note, *A Comparison of International Regulation of Preimplantation Genetic Diagnosis and a Regulatory Suggestion for the United States*, 15 TRANSNAT'L L. & CONTEMP. PROBS. 757, 779 (2006); Note, *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574 (2006).

each of these three questions, starting with an examination of the medical and social risks associated with PGS. Given these risks, the Article critiques the current lack of oversight in the United States. It then examines the ability of existing regulatory options to address the coming dilemma of reproductive genetic selection. Finding the current options wanting, the Article concludes with an outline for the development of a regulatory infrastructure for ART.

The proposed regulatory infrastructure is based upon the relevant stakeholders and their interests. With respect to PGS, the stakeholders include prospective parents, ART providers, children born via the procedure, and members of society affected by its use. To balance and protect their interests, this Article argues for the creation of an independent federal entity, the Assisted Reproductive Technology Authority (ARTA). Initially, ARTA should pursue regulation that will benefit all or most stakeholders, such as ensuring the safety and efficacy of all procedures involved in ART; improving access to information regarding the risks and benefits of various uses of ART; and analyzing the effect of ART, especially PGS, on both individuals and society.

ARTA should then focus on developing a framework to address stakeholders' conflicting interests. The most glaring conflict associated with PGS will arise from parental and practitioner desires to conduct procedures or screen embryos in ways that threaten harm to other individuals or society as a whole. Initially, ARTA should monitor the use patterns of ART and PGS to determine whether these interests conflict in ways that will result in substantial harm to other members of society. As PGS use expands, it will be imperative to have a working infrastructure to monitor potential harms and address these conflicts as they arise.

While the full scope of ethical, social, and technological challenges associated with ART and PGS is not yet visible, as is common at the outset of the use of most disruptive technologies, the United States can take steps to address current concerns associated with the technology and prepare for future dilemmas. Establishing the principles on which to base policy decisions in the future, as well as the infrastructure required to do so, will greatly improve the ability to assimilate and respond quickly to new information on the scientific developments, health risks, and public sentiment associated with PGS. Given the potential of these recent technological advances to alter our reproductive practices dramatically and permanently, we can no longer ignore the questions of whether and how we should regulate ART and, more specifically, PGS.

Rather than leaving regulation to professional societies, states, or Congress, the United States can best monitor and regulate ART via an independent federal agency. Unlike prior calls for change, this Article proposes a novel balancing approach to guide the way the federal agency addresses expanding PGS technology, along with a mechanism for monitoring the effects of PGS on individuals and society. Part I provides background information on the current

and future capabilities of PGS. Part II argues that PGS should be subject to oversight and regulation, and Part III considers which entities are best suited to oversee PGS. Finally, Part IV proposes a structure and an agenda for a new regulatory agency to govern ART practice in the United States.

I. PREIMPLANTATION GENETIC DIAGNOSIS AND SCREENING

PGD currently offers prospective parents the opportunity to select embryos based on their susceptibility to a range of genetic and chromosomal disorders, such as Down syndrome,²¹ Tay-Sachs,²² and cystic fibrosis.²³ To perform PGD, parents must go through a cycle of IVF, in which a clinician harvests a number of eggs from the woman and combines each with sperm in a Petri dish in hopes of producing healthy embryos. Some eggs will not fertilize successfully; others will be fertilized, but will not successfully divide. For those embryos that successfully divide, on the third day of growth, when they consist of about eight cells, the clinician will perform an embryo biopsy to remove a cell or two for genetic or chromosomal testing.²⁴ The testing must be completed within about forty-eight hours for the embryo to remain useful.²⁵

21. Down syndrome impacts one in 733 live births. Nat'l Down Syndrome Soc'y, Information Topics, http://www.ndss.org/index.php?option=com_content&task=view&id=1812&Itemid=95 (last visited Mar. 30, 2008). The disease is associated with impairment of physical growth, reduced cognitive ability, congenital heart defects and distinctive facial features. Nat'l Inst. of Child Health & Human Dev., Down Syndrome, http://www.nichd.nih.gov/health/topics/Down_Syndrome.cfm (last visited Apr. 5, 2008).

22. Tay-Sachs disease causes a relentless deterioration of mental and physical abilities. Over time, the disease inhibits the child's ability to see, hear, and swallow. The muscles progressively deteriorate, and paralysis eventually results. Most children die by the age of four. *See, e.g.*, Medline Plus, Tay-Sachs Disease, <http://www.nlm.nih.gov/medlineplus/taysachsdisease.html> (last visited Mar. 15, 2008).

23. Cystic fibrosis is a genetic disease that affects the mucus and sweat glands. Sticky mucus caused by the disorder leads to impairment throughout the entire body, affecting the lungs, pancreas, liver, intestines, sinuses, and sex organs. These difficulties persist over the life of the individual; with treatment, individuals with cystic fibrosis generally live longer than thirty-five years. *See* Medline Plus, Cystic Fibrosis, <http://www.nlm.nih.gov/medlineplus/cysticfibrosis.html> (last visited Mar. 15, 2008).

24. *See, e.g.*, IVF-Infertility.com, Preimplantation Genetic Diagnosis (PGD), <http://www.ivf-infertility.com/ivf/pgd.php> (last visited Apr. 5, 2008).

25. The embryo should then be transferred to the uterus on or before the fifth day after fertilization. As a result, genetic testing laboratories have less than a forty-eight-hour window to receive DNA samples from the embryo, conduct the genetic tests, and provide the results to the PGS clinic and transfer the embryo to the uterus of the woman for implantation. Interview with Barry Behr, Director, IVF/ART Laboratories, Dep't of Obstetrics & Gynecology, Stanford Sch. of Med., in Palo Alto, Cal. (Oct. 16, 2006).

After getting the test results, the clinician usually transfers two to three embryos that meet the parents' approval to the uterus in hopes of establishing pregnancy.²⁶ Embryos with undesired genes are typically discarded or donated to research.²⁷ Over 12,000 cycles of PGD have been performed worldwide since its creation in 1989, with the number of cycles growing substantially every year.²⁸

A. Current PGS Use

Scientists can now examine DNA through a number of different methods, each with its own benefits and drawbacks for PGS use. Different tests are used depending on whether the goal is to examine the chromosomes or the genes. Chromosomal structure analysis, performed by fluorescence in situ hybridization (FISH), examines whether the embryo has two copies of a chromosome and whether those copies are intact.²⁹ While FISH analysis provides useful information on common chromosomal abnormalities, it cannot provide information on all forty-six chromosomes because only five to nine chromosomes can be examined accurately at one time.³⁰ To examine a specific gene on a chromosome, geneticists have to make numerous copies of the DNA

26. Requirements for an embryo to meet parents' approval vary, including having the correct number of chromosomes, being the desired sex or tissue type, or being unaffected with a genetic disease.

27. Interview with Barry Behr, *supra* note 25.

28. See SUSANNAH BARUCH, DAVID KAUFMAN & KATHY L. HUDSON, GENETICS & PUB. POLICY CTR., *GENETIC TESTING OF EMBRYOS: PRACTICES AND PERSPECTIVES OF U.S. IVF CLINICS 3* (2006), available at <http://www.dnapolicy.org/resources/PGDSurveyReportFertilityandSterilitySeptember2006withcoverpages.pdf> (reporting a survey of "substantially all" U.S. ART clinics; 45% of these clinics responded, and together these clinics reported conducting 3379 cycles of PGS in 2005); Yury Verlinsky et al., *Over a Decade of Experience with Preimplantation Genetic Diagnosis: A Multicenter Report*, 82 FERTILITY & STERILITY 292, 293 (2004) (reporting in August 2004 that 4748 cycles of PGD had been performed in three of the world's most active PGD centers). According to a recent report from ESHRE, forty-five clinics worldwide conducted 12,397 cycles of PGD and PGS between 1997 and 2004, with 3358 performed in 2004 alone. J.C. Harper et al., *ESHRE PGD Consortium Data Collection VII: Cycles from January to December 2004 with Pregnancy Follow-Up to October 2005*, 23 HUM. REPROD. 741, 742 (2008). If this rate has remained fairly constant, I conservatively estimate that at least 25,000 cycles of PGD have been performed worldwide to date.

29. See Dagan Wells & Brynn Levy, *Cytogenetics in Reproductive Medicine: The Contribution of Comparative Genomic Hybridization (CGH)*, 25 BIOESSAYS 289, 291-92 (2003). FISH detects chromosomal abnormalities by labeling DNA probes that are perfect complements to the chromosomal region of interest with a fluorescent molecule. When mixed with sample DNA from the embryo, the probes will attach to their complementary chromosomal region on the embryo DNA, and the fluorescent molecules will emit colored signals to indicate certain abnormalities.

30. *Id.*

region of interest through a process known as polymerase chain reaction (PCR).³¹ Conducting PCR for a single gene takes a significant amount of time, which limits the number of tests that can be performed during the forty-eight hours available for testing.³²

1. Chromosomal Analysis

Chromosomal abnormalities can cause embryo death or lead to significant disorders in children.³³ While normal embryos have twenty-two pairs of autosomal chromosomes and one pair of sex chromosomes, abnormal embryos often have too many or too few copies of a chromosome, a condition known as aneuploidy. The most serious aneuploidies are lethal. PGS has been used to improve fertility by allowing parents to avoid the transfer of aneuploid embryos.³⁴ In current IVF practice, clinicians examine the shape and structure of embryos to determine which embryos are healthiest.³⁵ This physical examination, otherwise known as morphology analysis, fails to identify chromosomal abnormalities that occur in approximately 30% to 60% of embryos in women over thirty-five.³⁶ In theory, PGS should improve IVF success rates by allowing clinicians to identify chromosomal abnormalities that are undetectable by looking at the physical features of the embryo, although whether this improvement occurs in practice has been the subject of recent debate within the ART community.³⁷

31. See, e.g., Harper et al., *supra* note 28, at 746-47 (listing numerous conditions for which PCR is used); C.S. Salvado, A.O. Trounson & D.S. Cram, *Towards Preimplantation Diagnosis of Cystic Fibrosis Using Microarrays*, 8 REPROD. BIOMEDICINE ONLINE 107, 107-08 (2003).

32. Interview with Barry Behr, *supra* note 25.

33. March of Dimes, Chromosomal Abnormalities, http://www.marchofdimes.com/professionals/14332_1209.asp (last visited Apr. 5, 2008).

34. See V. Baltaci et al., *Relationship Between Embryo Quality and Aneuploidies*, 12 REPROD. BIOMEDICINE ONLINE 77 (2005); Y. Verlinsky et al., *Preimplantation Testing for Chromosomal Disorders Improves Reproductive Outcome of Poor-Prognosis Patients*, 11 REPROD. BIOMEDICINE ONLINE 219 (2005). But see Mastenbroek et al., *supra* note 16, at 13 (demonstrating that PGS use to screen for chromosomal abnormalities in infertile women of advanced maternal age decreased the likelihood that the woman will become pregnant when compared to traditional IVF).

35. Embryos with a more spherical shape that have progressed to a mature blastocyst state with evenly sized cells may be more promising candidates for transfer to the uterus. See, e.g., Baltaci et al., *supra* note 34, at 77; Santiago Munné, *Chromosome Abnormalities and Their Relationship to Morphology and Development of Human Embryos*, 12 REPROD. BIOMEDICINE ONLINE 234, 245 (2006).

36. Munné, *supra* note 35, at 245 (2005) (finding a chromosomal abnormality frequency of 30% for women aged thirty-five to thirty-nine and 60% for women over forty).

37. See *id.* at 248. But see Mastenbroek et al., *supra* note 16, at 15-17. The medical evidence does not yet fully support the idea that PGS can improve IVF success rates. Clinicians disagree about whether the improvement in embryo selection provided by PGS outweighs any additional

The use of PGS to screen for chromosomal structure can also detect which embryos will develop significant disorders. Infants can survive with three copies

risk to the embryo development caused by conducting the embryo biopsy required for PGS. Mastenbroek et al. found that in women of advanced maternal age, PGS was associated with reduced ongoing pregnancy rates from 37% to 25%, and reduced live birth rates from 35% to 24% when compared with traditional IVF. *Id.* at 13. This study is the second large, multi-center, randomized controlled trial to investigate the benefits of PGS in women of advanced maternal age, a large subset of the infertility population. *Id.* at 10, 15. Despite these results, the underlying theory that selecting embryos based upon the presence of an intact set of chromosomes should improve pregnancy and live birth rates has not been disputed. Mastenbroek et al. offered numerous possible explanations for the difference in pregnancy rates. *Id.* at 15-17. First, the embryo biopsy hindered implantation and development. *Id.* at 16. This could result from either the removal process in general or the technique used by researchers. Other PGS practitioners have questioned the quality of the embryo biopsy procedures performed, as approximately 20% of embryos in the PGS group had “undetermined” chromosomal status compared with 5% in experienced laboratories. *See id.* at 16 tbl. 4; *Preimplantation Genetic Diagnosis Pioneers from the USA and Europe Refute New England Journal of Medicine Article*, Med. News Today, July 10, 2007, <http://www.medicalnewstoday.com/articles/76269.php> [hereinafter *PGD Pioneers*]. When transferred, these embryos had only a 6% implantation rate, significantly lower than that of chromosomally “normal” PGS embryos (16.8%) and IVF embryos that did not undergo PGS (14.8%). Mastenbroek et al., *supra* note 16, at 15-16. Of the 642 embryos transferred to the uterus after PGS in this study, 100 were of undetermined status; this lowered the implantation, pregnancy and live birth rates associated with PGS in the study. *Id.* at 13; *PGD Pioneers, supra*. Secondly, researchers tested only one-third of the chromosomes, enabling some chromosomally abnormal embryos to be classified as “normal” and transferred. Mastenbroek et al., *supra* note 16, at 11, 16. These challenges can be alleviated through the use of DNA microarrays, and other advances in genetic testing technology can provide information on all twenty-three pairs of chromosomes. *Id.* at 16. Third, embryos created through IVF tend to be mosaic, a condition in which not all cells in the embryo have the same chromosomal structure, which can cause errors in classification. *Id.*; *see also supra* note 18 and accompanying text. For instance, a mosaic embryo with a majority of normal cells could be labeled “abnormal.” Improvements in genetic testing and embryo biopsy procedures may enable researchers to identify mosaic embryos in the future. Finally, more embryos from the PGS group were formed through ICSI than in the control group, also potentially compromising the integrity of the PGS embryos. Mastenbroek et al., *supra* note 16, at 16 tbl. 4. More research should be performed to determine the cause of the reduction in pregnancy and live birth rates. In the meantime, PGS use for infertility should be performed only in cases of repeat miscarriage and recurrent IVF failure. The use of PGS for infertility is most beneficial for couples that have experienced repeated miscarriages or otherwise have a poor prognosis related to the chromosomes. *See Verlinsky et al., supra* note 34, at 221 (demonstrating that in a group of poor-prognosis patients, PGS increased the implantation rate five-fold, cut the rate of spontaneous abortion by more than half, and more than doubled the take home baby rate in comparison to prior IVF cycles); *see also* Santiago Munné et al., *Preimplantation Genetic Diagnosis Significantly Reduces Pregnancy Loss in Infertile Couples: A Multicenter Study*, 85 FERTILITY & STERILITY 326, 329 (2006).

(trisomies) of chromosomes 8, 9, 13, 18, and 21 and substantial deletions (monosomies or partial monosomies) of regions on chromosomes 4, 5, and 15.³⁸ Each trisomy or monosomy is associated with a specific disorder, most of which result in mental retardation and premature death.³⁹ The most common aneuploidy disorder is Down syndrome (trisomy 21).⁴⁰ In addition to having too many or too few copies of a chromosome, abnormalities can also result when chromosomes break and, in some cases, reattach to other chromosomes – chromosomal translocation – which can lead to certain kinds of cancer and other abnormalities.⁴¹

Chromosomal testing can also be used for sex selection. Because males have only one copy of the X chromosome, mutations on that chromosome can result in disorders in male offspring.⁴² Sex selection is often performed to select against

38. Trisomies include Trisomy 8 (Warkany Syndrome), Trisomy 9, Trisomy 13 (Patau Syndrome), Trisomy 18 (Edwards Syndrome), Trisomy 21 (Down Syndrome), and Trisomy 22 (Cat's Eye Syndrome); monosomies include Monosomy 4 (Wolf-Hirschhorn Syndrome), Monosomy 5 (Cri du chat), Monosomy 15 (Angelman Syndrome/Prader-Willi Syndrome). See Genetics Home Reference, Cri-du-chat Syndrome, <http://ghr.nlm.nih.gov/condition=criduchatsyndrome> (last visited Apr. 18, 2008); Genetics Home Reference, Prader-Willi Syndrome, <http://ghr.nlm.nih.gov/condition=praderwillisyndrome> (last visited Apr. 18, 2008); Healthline, Trisomy 8 Mosaicism Syndrome, <http://www.healthline.com/galecontent/trisomy-8-mosaicism-syndrome> (last visited Apr. 18, 2008); Medline Plus, Down Syndrome, <http://www.nlm.nih.gov/medlineplus/downsyndrome.html> (last visited Apr. 18, 2008); Medline Plus, Trisomy 13, <http://www.nlm.nih.gov/medlineplus/ency/article/001660.htm> (last visited Apr. 18, 2008); Medline Plus, Trisomy 18, <http://www.nlm.nih.gov/medlineplus/ency/article/001661.htm> (last visited Apr. 18, 2008); Online Mendelian Inheritance in Man, Wolf-Hirschhorn Syndrome, <http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=194190> (last visited Apr. 18, 2008); WebMD, Chromosome 9, Trisomy Mosaic, <http://children.webmd.com/chromosome-9-trisomy-mosaic> (last visited Apr. 18, 2008); WebMD, Chromosome 22, Trisomy Mosaic, <http://children.webmd.com/chromosome-22-trisomy-mosaic> (last visited Apr. 18, 2008).

39. See sources cited *supra* note 38.

40. See National Down Syndrome Society, *supra* note 21; see also Online Mendelian Inheritance in Man, Down Syndrome, <http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=190685> (last visited Mar. 31, 2008).

41. The Philadelphia chromosome is an example of a reciprocal translocation where a portion of both the ninth chromosome and the twenty-second chromosome break off and reattach on the other chromosome. The Philadelphia chromosome causes the malignant transformation in chronic myelogenous leukemia, a form of cancer that weakens a patient's immune system and ability to fight infection. See Michael Savona & Moshe Talpaz, *Getting to the Stem of Chronic Myeloid Leukaemia*, 8 NATURE REV. CANCER 341 (2008); Online Mendelian Inheritance in Man, Leukemia, Chronic Myeloid, <http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=608232> (last visited Mar. 31, 2008).

42. Richard Twyman, *X-Linked Diseases*, HUM. GENOME, Apr. 16, 2003, http://genome.wellcome.ac.uk/doc_wtd020851.html.

all male embryos produced by a couple at risk for X-linked disorders in cases where no specific genetic test for the disorder exists.⁴³ As scientists develop more specific gene tests for disorders on the X chromosome, the need for sex selection for medical purposes will decrease. Sex selection for non-medical purposes, such as family balancing, however, continues to increase.⁴⁴

Chromosomal analysis for medical purposes represents the most common use of preimplantation screening in the United States. The Genetics and Public Policy Center in Washington, D.C. recently surveyed 137 ART clinics in the United States and found that out of the 3379 PGD cycles they performed in 2005, 66% of the cycles were for aneuploidy (2197), 9% were for chromosomal translocations (403), and 3% were for X-linked diseases (96).⁴⁵ The Genetics and Public Policy Center also found that 42% of ART clinics reported that they had enabled parents to choose the sex of their child for non-medical reasons, such as family balancing or parental preference.⁴⁶ In addition, after undergoing PGS to screen their embryos for chromosomal disorders, 35% of clinics gave parents the option to select girls and boys for implantation from among the remaining healthy embryos.⁴⁷

2. Genetic Analysis

In contrast to analyzing entire chromosomes, clinicians can also use PGD to look for specific genetic traits. The Genetics and Public Policy Center survey found that clinicians performed 12% of PGD procedures to avoid transferring embryos that would develop severe genetic disorders,⁴⁸ such as Fanconi anemia,⁴⁹ cystic fibrosis, and Tay-Sachs. Often these disorders begin early in life and have no known cure. Couples have also begun to screen embryos for late-onset conditions that do not present until adulthood, such as Huntington's disease

43. BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 5.

44. *See id.* at 6 (indicating that "sex selection [was] frequently mentioned" as a source of "ethical questions" for clinics).

45. *See id.* at 3.

46. *Id.*

47. *Id.* at 6.

48. *See id.* at 4 (stating that 12% of reported cycles were provided to detect autosomal single gene disorders).

49. Fanconi anemia is a rare, recessive blood disorder that is associated with an increased incidence of tumor growth and failure of the bone marrow to produce blood cells. Many patients develop acute myelogenous leukemia and die at a young age (between twenty and thirty years). Nat'l Heart & Lung Inst., Disease and Conditions Index, What Is Fanconi Anemia?, http://www.nhlbi.nih.gov/health/dci/Diseases/fanconi/fanconi_what.html (last visited Mar. 30, 2008); *see also* Harper et al., *supra* note 28, at 743-44 (grouping Fanconi anemia in a list of monogenic diseases).

and Alzheimer's disease, and for genetic predispositions to diseases like hereditary breast cancer and colon cancer.⁵⁰

Genetic analysis can also permit parents to select embryos based on their non-medical traits. Couples have undergone PGS to select an embryo that could be a cord blood donor for a sick family member by virtue of having the same genetic Human Leukocyte Antigen (HLA) or tissue type.⁵¹ In families with a history of a genetic disorder, such as Fanconi anemia, parents can use PGS to select unaffected embryos that can be tissue donors for their sick child. If the sick child has a disease without a genetic cause, parents can also use PGS solely to select embryos that could be a tissue type match for the sick child. This use of PGS has inspired much ethical debate around whether it is appropriate to create a child to save another, or to put the future child at risk to save another.⁵² Only 6% of ART clinics surveyed have provided tissue typing in the absence of testing for a genetic disorder.⁵³

Some individuals have sought to use PGS to select embryos that will fit into their culture by choosing embryos that have a specific genetic condition, such as deafness or acondroplasia (dwarfism).⁵⁴ Three percent of ART clinics surveyed have enabled couples to use PGS to select for disabilities.⁵⁵ While embryo selection for non-medical purposes still remains a small percentage of overall PGS use, this type of selection will continue to grow as the number of genetic tests increases and public knowledge of PGS expands.

B. Limitations on Current PGS Use

Currently PGS has a number of drawbacks that limit its use. The largest of these results from its reliance on the IVF process to create embryos for genetic and chromosomal testing. IVF is expensive and unpleasant. One cycle of IVF ranges in price from \$10,000 to \$12,000.⁵⁶ While a handful of states require insurance companies to cover all or a portion of the costs associated with IVF, a substantial percentage of IVF patients remain uncovered by insurance and are

50. See BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 4.

51. *Id.* at 5.

52. See, e.g., S. Sheldon & S. Wilkinson, *Should Selecting Saviour Siblings Be Banned?*, 30 J. MED. ETHICS 533 (2004). The United Kingdom originally banned the use of PGS solely to create a child with a matching tissue type, but then overturned the decision in light of public outcry and more liberal policies in other countries.

53. See BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 5.

54. *Id.*; see also Darshak M. Sanghavi, *Wanting Babies Like Themselves, Some Parents Choose Genetic Defects*, N.Y. TIMES, Dec. 5, 2006, at F5.

55. See BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 5.

56. BARUCH ET AL., *supra* note 17, at 22.

forced to pay for the procedure out of pocket.⁵⁷

Given the discomfort and inconvenience associated with IVF,⁵⁸ women may be reluctant to try PGS. In order to stimulate the ovaries to produce eggs for the IVF cycle, women must undertake daily hormone injections for ten to twelve days.⁵⁹ The mature eggs must be retrieved through a minor surgical procedure conducted under sedation or anesthetic.⁶⁰ Egg retrieval can result in pain, bleeding, nausea, and vomiting.⁶¹ In addition, the long-term risks of fertility drugs remain largely unexamined and unknown.⁶²

In addition to the problems associated with IVF, certain features of PGS also limit its use. PGS testing adds an additional \$2500-\$7000 to the price of IVF, making it even more financially inaccessible.⁶³ Second, the embryo biopsy procedure may hinder embryo implantation and development, reducing live birth success rates.⁶⁴ Finally, the amount of information currently available through PGS testing is significantly constrained by genetic testing restrictions and the fragile state of the preimplantation embryo.⁶⁵ Having only the biopsied cell's DNA available for testing greatly limits testing options and accuracy. Currently, couples must choose between conducting an analysis on five to nine chromosomes and conducting one to two genetic tests,⁶⁶ as these tests examine

57. DEBORAH SPAR, *THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION* 213 (2006).

58. See, e.g., IVF-Infertility.com, Egg Collection, <http://www.ivfinfertility.com/ivf/standard/procedure/egg.php> (last visited Apr. 4, 2008); IVF-Infertility.com, Superovulation, <http://www.ivf-infertility.com/ivf/standard/procedure/superovulation.php> (last visited Apr. 4, 2008).

59. See IVF-Infertility.com, Superovulation, *supra* note 58. In up to 3% of women, these hormones can result in moderate or severe ovarian hyperstimulation, a serious condition that results in hospitalization and in rare cases death. See David A. Grainger, Linda M. Fraizer & Courtney A. Rowland, *Preconception Care and Treatment with Assisted Reproductive Technologies*, 10 *MATERNAL & CHILD HEALTH J.* S161, S162 (2006). Some researchers and patients are concerned that fertility drugs may lead to an increased risk of hormone-dependent cancers, such as breast, ovarian, and uterine cancers. While the limited research that has been done does not support a relationship between fertility drugs and breast and ovarian cancer, more research is imperative to determine the long-term cancer risks of fertility drugs. See *ASSESSING THE MEDICAL RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH: WORKSHOP REPORT 2* (Linda Giudice, Eileen Santa & Robert Pool eds., 2007), available at http://www.nap.edu/catalog.php?record_id=11832 [hereinafter *WORKSHOP REPORT*].

60. See IVF-Infertility.com, Egg Collection, *supra* note 58.

61. *Id.*

62. *WORKSHOP REPORT*, *supra* note 59, at 2.

63. Reprod. Genetics Inst., Price List as of 1/05, www.reproductivegenetics.com/docs/pgd_pricelist_022305.pdf (last visited Mar. 31, 2008).

64. See Mastenbroek et al., *supra* note 16.

65. See *supra* note 25.

66. BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 2.

the DNA in different ways. These technological constraints have greatly limited the information PGS can provide prospective parents, and therefore the use of the procedure in general.

Even if scientists resolve these technical dilemmas, current understanding of gene function and how genes produce certain physical characteristics or phenotypes is also limited. For most common heritable diseases, like heart disease and diabetes, the genetic contribution to the development of the disorder is complicated. “[T]he interplay of multiple genes and multiple non-genetic factors, not a single allele, usually dictates disease susceptibility and response to treatments.”⁶⁷ Computer scientists, geneticists, and statisticians are developing strategies to decipher the role of gene-gene interaction and gene-environment interaction in common disorders and individual characteristics.⁶⁸ As our understanding of these interactions expands along with our ability to test for numerous genes at one time, the value of the information PGS can provide to couples will grow quickly and exponentially.

Alleviating these technical and informational difficulties may tip the balance for many couples in favor of using PGS. This hope of an increased market demand has inspired numerous scientists to try to resolve the technical and financial challenges associated with PGS.

C. Future Capabilities of PGS

Even with current limitations, recent innovations in genetic testing will soon increase the information available to prospective parents through PGS by enabling them to simultaneously evaluate embryos on both their chromosomal integrity and the presence of numerous gene variants.⁶⁹ The most promising advance involves the use of DNA microarrays. A DNA microarray provides a medium for the orderly arrangement and matching of known and unknown DNA samples.⁷⁰ When performed for a full sample of DNA, microarrays can identify

67. Francis S. Collins et al., U.S. Nat’l Hum. Genome Res. Inst., *A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era*, 422 NATURE 835, 840 (2003).

68. *Id.* at 838; *New Technology Predicted To Revolutionize Genetic Analysis of Preimplantation Embryos*, MED. NEWS TODAY, Oct. 22, 2006, <http://www.medicalnewstoday.com/articles/54745.php> [hereinafter *New Technology Predicted*].

69. See Munné, *supra* note 35; Dagan Wells, *Advances in Preimplantation Genetic Diagnosis*, 115 EUR. J. OBSTETRICS & GYNECOLOGY & REPROD. BIOLOGY S97 (Supp. I 2004); *New Technology Predicted*, *supra* note 68.

70. Salvado, Trounson & Cram, *supra* note 31, at 108. Microarrays are easier to conduct than FISH and more sensitive, in some cases increasing the resolution to 100-200 kilobases. Wells & Levy, *supra* note 29, at 297. The presence of either normal or abnormal genetic variations in a sample can be detected by allowing the sample DNA to bond with complementary DNA that codes for the respective variations. Microarrays permit geneticists to test for the presence of numerous

mutations and abnormalities at the level of the chromosome, gene or even single nucleotide polymorphism.⁷¹ Geneticists have developed a new technique, array-based comparative genomic hybridization, to screen for small sequences of DNA in a manner that will enable them to examine the integrity of all forty-six chromosomes as well as hundreds of genes from a single embryonic cell.⁷² While this procedure is relatively new and has not been performed clinically in ART, the future of PGS lies in screening technology that can provide complete chromosomal information along with significant DNA sequencing information from one cell in forty-eight hours or less.

The ability to combine chromosomal analysis with specific gene tests will revolutionize PGS. Couples undergoing PGD to select against embryos affected with a serious genetic disorder will be able to select from the remaining unaffected embryos based upon a range of characteristics. While PGD was initially created for disorders that were guaranteed to develop if the gene was present,⁷³ PGS will rely much more heavily on detecting genes that increase the probability that a disorder will develop.

The shift to probability is occurring because the vast majority of human characteristics or conditions with any genetic component are multigenic and multifactorial.⁷⁴ As scientists' understanding of genetics develops, they will be able to create statistical models that use the presence of numerous gene variants to provide a more complete picture of an embryo's probability of developing a specific disorder or condition.⁷⁵ This type of genetic modeling could be used to

genetic variants at one time by placing hundreds of complementary sequences of DNA onto the array and then permitting the sample DNA to bind with its complementary sequences. Salvado, Trounson & Cram, *supra* note 31, at 112.

71. Salvado, Trounson & Cram, *supra* note 31, at 112. A single nucleotide polymorphism (SNP) is a change in the single nucleotide, the building block of DNA. A single gene will often have thousands of nucleotides. See Human Genome Project Information, Information, http://www.ornl.gov/sci/techresources/Human_Genome/publicat/primer/prim1.html (last visited Apr. 18, 2008); Human Genome Project Information, SNP Fact Sheet, http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml (last visited Apr. 18, 2008).

72. See Wells & Levy, *supra* note 29.

73. See BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 1.

74. See Collins et al., *supra* note 67, at 840.

75. See, e.g., Marylyn D. Ritchie et al., *Optimization of Neural Network Architecture Using Genetic Programming Improves Detection and Modeling of Gene-Gene Interactions in Studies of Human Diseases*, 4 BMC BIOINFORMATICS 28 (2003), <http://www.biomedcentral.com/1471-2105/4/28>; Quanhe Yang et al., *Improving the Prediction of Complex Diseases by Testing for Multiple Disease-Susceptibility Genes*, 72 AM. J. HUM. GENETICS 636, 644 (2003). For instance, if seventeen genes are associated with heart disease, knowledge of the allelic makeup of all seventeen genes and how much each allele contributes to the development of heart disease could provide prospective parents with valuable information on the likelihood that a specific embryo would

provide probability information on all types of genetic traits, as well as to inform parents regarding the potential impact of certain environmental stimuli.

Improvements in our understanding of gene function will also provide information on non-disease-related genetic traits, such as height, hair color, skin color, eye color, and possibly some behavioral characteristics. Geneticists investigating pigmentation in skin, hair, and eyes are beginning to make substantial discoveries.⁷⁶ The genetic determinants of behavior are much more complex, but scientists may discover genes that govern certain behavioral characteristics through research into psychiatric disorders and other conditions.⁷⁷

The future capabilities of PGS are best described by a hypothetical. Imagine a couple that, because of fertility problems, plans to use IVF. The clinician harvests fourteen eggs from the prospective mother and fertilizes them with the prospective father's sperm. Ten of the eggs are successfully fertilized, and eight of those develop normally to the eight-cell stage. At that point, PGS is used to screen the eight remaining embryos for various chromosomal and genetic conditions. Results might indicate that chromosomal defects exist in embryos 1, 3, and 8 that make it unlikely that those embryos would result in a live birth. Embryo 2 can produce a baby, but the child would have Down syndrome. Embryo 6 would have cystic fibrosis. Embryos 1, 2, and 8 would carry one copy of the cystic fibrosis gene, which would not affect them but could result in their offspring having the disease. Embryos 5 and 7 have twice the normal chance of developing Alzheimer's disease in older age; embryos 1 and 7 have double the normal risk of breast cancer. Embryos 1, 3, 4, and 7 are female; embryos 3, 4, and 7 would likely be taller than average; embryos 1, 4, and 8 would have blue eyes.

Physicians are likely to present their patients with charts describing the characteristics of each of their embryos and offer them genetic counseling services to ensure that they understand the risks associated with each condition. At some point, the potential advantages of avoiding disease, limiting disease risks, and choosing non-disease traits may make PGS (even with its associated need for IVF) worthwhile even for fertile couples who are not at any known risk for children with a serious genetic disease. For many couples, "more information about the medical status of embryos and pregnancies is likely to be perceived as preferable," even if it is only probabilities.⁷⁸ While PGS presents prospective couples with numerous potential benefits, it also poses some significant risks.

In deciding whether to intervene in reproductive aspects of citizens' lives,

develop heart disease. In some cases, this could be as high as 90% or more.

76. See Bastiaens et al., *supra* note 9; Duffy et al., *supra* note 9.

77. Ridha Joobar, Sarojini Sengupta & Patricia Boksa, *Genetics of Developmental Psychiatric Disorders: Pathways to Discovery*, 30 J. PSYCHIATRY & NEUROSCIENCE 349, 351-52 (2005).

78. Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 558.

the government should consider the nature of the people involved and the potential for government intervention to improve their situation. The people put at risk by unrestricted PGS use are some of the most vulnerable in American society: the disabled, the poor, children, the infertile, the stigmatized, and prospective parents desperate for a healthy child. The government has an obligation to protect the interests of vulnerable groups in the face of risks put upon them by the actions of others. For each vulnerable group, extending government oversight – whether to reduce discrimination, increase access, mitigate health risks, or provide better information – should reduce the risk of harm.

II. IS PGS OVERSIGHT NECESSARY?

In order to protect vulnerable groups, the government must first decide how extensively to intervene into the lives of its citizens. If the government limits the freedom of individuals to use a technology, it should do so in a principled, systematic manner.⁷⁹ The principles the government selects as the foundation of its regulatory agenda will determine the scope of the potential public policy. As the regulation of assisted reproductive technologies affects some of the most important and personal decisions of the citizenry, the government should exercise caution when deciding whether and how to intervene.⁸⁰

A. The Authority of Society over the Individual

In determining the extent to which the government should regulate the use of PGS by prospective parents, John Stuart Mill's discussion of the limits of the authority of society over the individual is instructive.⁸¹ Mill argues that "[a]s soon as any part of a person's conduct affects prejudicially the interests of others, society has jurisdiction over it, and the question whether the general welfare will or will not be promoted by interfering with it becomes open to discussion."⁸² This general principle can be applied to define the boundaries of PGS regulation.

Mill's principle establishes a high threshold for governmental intervention that protects individual autonomy while not ignoring the interests of other

79. See ALAN BUCHANAN ET AL., FROM CHANCE TO CHOICE: GENETICS AND JUSTICE 4, 15 (2000) (discussing the need to identify basic moral principles to guide public policy, and noting that "institutional ethical principles . . . are most essential for a just and humane society equipped with robust capabilities for genetic intervention").

80. See *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 849 (1992) (holding that "the Constitution places limits on a State's right to interfere with a person's most basic decisions about family and parenthood").

81. J.S. MILL, ON LIBERTY 73-91 (Elizabeth Rapaport ed., Hackett Publ'g Co. 1978) (1863).

82. *Id.* at 73.

members of society. Under this approach, the government should intervene only if the use of PGS threatens unjust harm to either the individuals involved in the procedure⁸³ or the members of society affected by use of the procedure. The latter category might include those who do not have access to these technologies but must compete with those who do; those with diseases and conditions screened out by PGS who may receive less understanding and support from society; those who have to pay for others' medical care; and possibly those who are greatly disturbed by widespread use of these technologies.⁸⁴ Mill's libertarian standard generally opposes government intervention unless it is absolutely necessary;⁸⁵ regulations that would be acceptable under this standard represent the minimum that the government should do to oversee PGS. Many would argue that the government should do even more.

Federal and state governments have generally followed Mill's approach in regulating health care. They have been reluctant to interfere in individual medical decisions, intervening only when it has been necessary to protect the patient or society. For patients, the government has acted 1) to require physicians to provide patients with material information necessary to give informed consent;⁸⁶ 2) to ensure the competence or safety of the personnel, clinic, hospital, and laboratory providing medical care;⁸⁷ and 3) to eliminate the use of unsafe, ineffective, or counterfeit drugs.⁸⁸

When an individual's medical decision could negatively affect others, the

83. This includes both prospective parents and children. The government should intervene to protect parents from the potential harms caused by information asymmetries common in medical practice and from unsafe or ineffective health care practices.

84. Mill's original principle would not include "distaste," "outrage," or discomfort to others as a harm that constitutes grounds for governmental regulation. MILL, *supra* note 81, at 81-82. However, in this context, given the passionate nature of the debate over abortion and status of the embryo in the United States, I have elected to include this as a harm that should warrant government consideration and possibly intervention, albeit a harm of lesser value than other more direct harms caused by PGS.

85. *See id.* at 73-74, 76-77.

86. *See* Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429 app. at 493-501 (2006) (listing state informed consent statutes and relevant cases).

87. 42 U.S.C. § 263a(b) (2000) (requiring all laboratories that solicit or accept materials derived from the human body for laboratory examination to be certified).

88. 21 U.S.C. § 393(b) (2000) (stating that the mission of the FDA is to ensure the safety and efficacy of drugs and medical devices). Outside of medical treatment decisions, the government intervenes in the health care system significantly in its capacity as payor for Medicare and Medicaid services. As a payor, the government determines which services it will reimburse physicians for and at what rates. This has a substantial impact on the overall practice of medicine. *See, e.g.*, PAUL J. FELDSTEIN, *HEALTH POLICY ISSUES: AN ECONOMIC PERSPECTIVE* 109-13, 115-18, 202-03 (3d ed. 2003).

government has restricted the individual's autonomy to protect society. States may use their police power to quarantine individuals or mandate vaccinations in order to protect the public's health.⁸⁹ The government also has the power to regulate individual medical decisions based on non-health-related social interests.⁹⁰ With respect to reproductive autonomy, the Supreme Court in *Gonzales v. Carhart* recognized the right of the federal government to prohibit the use of a medical procedure, partial-birth abortion, on the basis of social interests in respecting the life of the unborn and protecting the integrity of physicians.⁹¹ To determine whether intervention is appropriate, the government must understand the individual and social risks associated with PGS.

B. Risks Associated with PGS

While PGS offers numerous benefits to prospective parents, its unfettered use threatens harm to both individuals and society. Although many of the known risks rarely materialize, these harms can be substantial for both the offspring and the parents, ranging from minor inconveniences to serious physical and mental disabilities and death. Expanding PGS use also raises social concerns regarding discrimination, disparities in access, and devaluing the embryo.

1. Risks to Offspring Born via PGS

Risks to offspring born via PGS result from the transfer of multiple embryos,⁹² the ART procedures used to create the embryo, like IVF and ICSI, and the embryo biopsy.⁹³ Although ART procedures used to give an individual life cannot be said to harm that individual, unless the life was not worth living, the risks associated with such procedures are important for physicians, patients, and the government to consider in making decisions regarding their use.⁹⁴

89. See, e.g., *Jacobsen v. Massachusetts*, 197 U.S. 11 (1905); *O'Neil v. State*, 32 So. 667 (Ala. 1902); see also Lawrence O. Gostin, Jeffery P. Koplan & Frank P. Grad, *The Law and the Public's Health: The Foundations*, in *LAW IN PUBLIC HEALTH PRACTICE* 3, 16 (Richard A. Goodman et al. eds., 2003).

90. See, e.g., *Gonzales v. Carhart*, 127 S. Ct. 1610, 1617 (2007) (holding that partial-birth abortion could be regulated for the purposes of "protecting innocent human life from a brutal and inhumane procedure and protecting the medical community's ethics and reputation").

91. *Id.*

92. See Klemetti et al., *supra* note 14, at 1821 (discussing the number of multiple births resulting from IVF).

93. See Sirpa Soini et al., *The Interface Between Assisted Reproductive Technologies and Genetics*, 14 EUR. J. HUM. GENETICS 588, 608-09 (2006).

94. DEREK PARFIT, *REASONS AND PERSONS*, 358-61 (1984) (describing the "non-identity problem" as the dilemma that an individual cannot be said to be harmed by a decision that led to his or her birth, unless the life was not worth living, which can be applied to parental decisions to use

Parents and clinicians often decide to transfer more than one embryo per cycle of IVF or PGS to improve success rates.⁹⁵ This practice increases the incidence of multiple births from 3% with natural conception to 33% with IVF,⁹⁶ and as a result, harms the overall health of children born via IVF.⁹⁷ In a study published in *Pediatrics*, Reija Klemetti and colleagues found that IVF infants “showed much worse” perinatal health indicators than naturally conceived children, which was partly explained by multiple gestations.⁹⁸ Klemetti found that IVF infants were more likely to be born through Cesarean section (35.8% vs. 15.3%), to be born preterm (23.6% vs. 5.5%), to have low birth weight (24% vs. 4.8%), to require treatment in the newborn intensive care unit (23% vs. 8.2%), to require hospitalization for seven days or more (23.8% vs. 6.4%), and to die perinatally (1.3% vs. 0.6%) compared to naturally conceived controls.⁹⁹ Practice guidelines or regulations limiting the number of embryos that clinicians can transfer could significantly reduce the incidence of adverse health outcomes associated with IVF multiple births, albeit at the cost of lowering the percentage of IVF cycles that result in a live birth.¹⁰⁰

ART that risk harm to the resultant child).

95. See Michael Le Page, *Fertility Experts Call for One Embryo per IVF Cycle*, NEW SCIENTIST, Oct. 18, 2006, <http://www.newscientist.com/channel/sex/dn10326-fertility-experts-call-for-one-embryo-per-ivf-cycle.html>.

96. CTRS. FOR DISEASE CONTROL & PREVENTION, 2004 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 22 (2006), available at <http://ftp.cdc.gov/pub/Publications/art/2004ART508.pdf> (stating that approximately 33% of all live births from IVF produced more than one infant (30% twins, 3% triplets or more) compared with 3% incidence in the normal population).

97. Bonduelle et al., *supra* note 15, at 416-18; Michèle Hansen et al., *The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and In Vitro Fertilization*, 346 NEW ENG. J. MED. 725, 727 (2002); Klemetti et al., *supra* note 14, at 1822 (2006); Soini et al., *supra* note 93, at 606-07.

98. Klemetti et al., *supra* note 14, at 1822. Perinatal health indicators are those surrounding the time of birth, both before and immediately after. Klemetti et al. found that nearly half of IVF infants born from multiple births required hospitalization beyond seven days (47.4% vs. 6.4%) and treatment in the NICU (42.1% vs. 8.2%) compared with naturally conceived infants. The risk of perinatal death also nearly quadrupled from 0.6% in naturally conceived infants to 2% in IVF infants from multiple births.

99. *Id.* at 1822 tbl. 2 (comparing 4559 infants conceived by IVF and 190,398 infants conceived naturally).

100. The American Society for Reproductive Medicine recently issued practice guidelines that recommend transferring a limited number of embryos based upon the woman’s age and reproductive history. See Practice Comm., Soc’y for Assisted Reprod. Tech. & Practice Comm., Am. Soc’y for Reprod. Med., *Guidelines on Number of Embryos Transferred*, 86 FERTILITY & STERILITY S51 (2006). Whether clinicians will abide by the voluntary guidelines remains in question as transferring fewer embryos reduces the pregnancy success rates of the procedure, which

However, practice guidelines and regulations limiting the number of embryos transferred cannot eliminate all of the risks associated with IVF and ICSI. Studies performed in the last few years have consistently shown that singleton babies born via IVF and ICSI also have higher rates of mortality, preterm delivery, congenital malformations, and low birth weight compared to naturally conceived babies.¹⁰¹ Likewise, by the age of five, IVF and ICSI children were more likely to have had a childhood illness and significantly more likely to have had a surgical operation than naturally conceived children.¹⁰² However, the data remain unclear as to what portion of the negative health outcomes of IVF and ICSI result from the underlying cause of parental infertility, rather than the ART procedures themselves.¹⁰³ While the health of IVF and ICSI children appears to be worse than naturally conceived children, it is not overwhelmingly so.¹⁰⁴ Nonetheless, these risks should be balanced against the relevant interests in undergoing IVF or ICSI.

In cases of infertility, the government should weigh the above risks against the parents' interests in having a healthy biological child and against the

is often undesirable for prospective parents and clinicians. Prospective parents likely prefer higher success rates per cycle, as they often pay for the procedure out of their own pocket and desire a child sooner rather than later. Clinicians may prefer higher success rates per cycle because clinics gain reputations based on the ratio of pregnancies and live births per cycle.

101. See Bonduelle et al., *supra* note 15; Halliday, *supra* note 14; Hvidtjorn et al., *supra* note 14; Klemetti et al., *supra* note 14; Mastenbroek et al., *supra* note 16. *But see* Tracy Hampton, *Panel Reviews Health Effects Data for Assisted Reproductive Technologies*, 292 JAMA 2961, 2961 (2004) (meta-analysis found "evidence generally suggestive of no association" between ART procedures and serious malformations); I. Ponjaert-Kristoffersen et al., *International Collaborative Study of Intracytoplasmic Sperm Injection-Conceived, In Vitro Fertilization-Conceived, and Naturally Conceived 5-Year-Old Child Outcomes: Cognitive and Motor Assessments*, 115 PEDIATRICS e283 (2005), <http://pediatrics.aappublications.org/cgi/reprint/115/3/e283> (finding no statistical difference between the cognitive and motor skills of children born via ICSI and naturally conceived children).

102. Bonduelle et al., *supra* note 15, at 417.

103. In October 2006, Professor Mary Croughan found that women who had experienced fertility problems had children with 2.7 times the risk of having autism, mental retardation, cerebral palsy, seizures and cancer than women without such conditions. *Infertility Link to Autism Risk*, BBC NEWS, Oct. 26, 2006, <http://news.bbc.co.uk/go/pr/fr/-/1/hi/health/6086824.stm>. For autism alone, Croughan and colleagues found that the risk increased 400% for offspring of patients with fertility problems. This research leaves open the contribution that procedures such as IVF and ICSI made to these negative health outcomes. Harms could have resulted from health problems already present in the parents, from the procedures they used to try to overcome their infertility, or from a combination of both.

104. See Bonduelle et al., *supra* note 15, at 415 (stating that "74% of ICSI children and 77% of IVF children experienced significant childhood illness compared with only 57% of [naturally conceived] children").

embryo's interest in being born. Are the risks to the embryo of being born with a higher risk of a disease or defect so great as to outweigh the benefit of life itself? The question of whether a child can be harmed by a procedure that gives it life has been the topic of debate among scholars and in many court cases.¹⁰⁵ While legal scholars continue to disagree on this issue, the majority of courts have refused to hear claims brought by children on the basis that they should not have been born, so called "wrongful life claims";¹⁰⁶ however, parents have successfully brought "wrongful birth claims" to recover the cost of raising a disabled child from physicians for failure to diagnose the disorder or prevent its occurrence.¹⁰⁷ Currently, the risks of IVF and PGS do not make an individual's life so miserable as to negate its value, therefore its use for fertility purposes remains appropriate in those populations where PGS can improve IVF success rates.¹⁰⁸ In contrast, in cases where IVF and PGS are not necessary for the parents to give birth, the risk to the child from the procedures should be weighed against the benefits of selecting for a certain characteristic.

More investigation is necessary to determine the full extent and magnitude

105. See, e.g., PARFIT, *supra* note 94, at 358-61 (describing the "non-identity problem"); Carl H. Coleman, *Conceiving Harm: Disability Discrimination in Assisted Reproductive Technologies*, 50 UCLA L. REV. 17, 56 (2002) (stating that it is "possible to object to efforts to bring about the birth of a child likely to suffer considerably even if the child, once born, would not consider her life a disadvantage"); Philip G. Peters, Jr., *Protecting the Unconceived: Nonexistence, Avoidability, and Reproductive Technology*, 31 ARIZ. L. REV. 487, 502-03 (arguing that a miserable life may be worth continuing, but not worth receiving); John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J.L. & MED. 7, 14 (2004) (arguing that if the child's life is not so miserable as to be wrongful, then the child would have benefited from being born, and the use of the ART cannot be restricted on the basis of harm to the child).

106. See, e.g., Walker *ex rel* Pizano v. Mart, 790 P.2d 735, 741 (Ariz. 1990) (holding that a child bringing a "wrongful life" claim had suffered no legally cognizable injury); Kassama v. Magat, 792 A.2d 1102, 1115-23 (Md. 2002) (noting that twenty-eight other states had rejected wrongful life claims); Viccaro v. Milunsky, 551 N.E.2d 8, 12 (Mass. 1990) (refusing to recognize a cause of action for wrongful life). A few jurisdictions will permit wrongful life claims. See, e.g., Galvez v. Fields, 107 Cal. Rptr. 2d 50, 57-59 (Cal. Ct. App. 2001) (noting that California explicitly acknowledges a child's right to bring a wrongful life claim); Harbeson v. Parke-Davis, Inc. 656 P.2d 483, 495 (Wash. 1983) (reasoning that "a child may maintain an action for wrongful life").

107. See, e.g., Keel v. Banach, 624 So. 2d 1022, 1026 (Ala. 1993) (recognizing a cause of action for wrongful birth); Turpin v. Sortini, 643 P.2d 954, 957 (Cal. 1982) (citing a number of cases in which parents were permitted to recover general damages for the wrongful birth of their children); Emerson v. Magendatnz, 689 A.2d 409 (R.I. 1997) (recognizing a parent's claim against a physician after a sterilization procedure failed); Noah, *supra* note 20, at 638-40.

108. These populations include couples that have experienced repeated miscarriages or otherwise have a poor prognosis related to chromosomal abnormalities. See Munné et al., *supra* note 37, at 329; Verlinsky et al., *supra* note 34, at 221.

PREDICTING PROBABILITY

of the risks associated with IVF. However, the known risks of IVF alone warrant regulation of uses outside of infertility to ensure that the benefits of the procedure outweigh the risks to both mother and offspring. Improved data collection and research regarding benefits and risks of PGS on the lives of children born through the technology is needed. Without such information, parents will continue to make under-informed decisions that may jeopardize the health of their children.

In addition to the risks from transferring multiple embryos and embryo creation, couples that use PGS may subject their offspring to additional harm caused by the embryo biopsy procedure. While the bulk of available evidence suggests that infants born via PGS have roughly similar health outcomes to those born via IVF, the question of whether removing cells for genetic testing harms development still looms over the practice of PGS.¹⁰⁹ Harm from the embryo biopsy was one of the first reasons suggested for the drop in live birth rates from 37% in IVF patients to 25% in IVF patients undergoing PGS as shown in a recent study from the Netherlands.¹¹⁰ Other scientists have suggested that imprecise or unskilled embryo biopsy can substantially harm the embryo, preventing implantation and development.¹¹¹ In addition, whether the embryo biopsy can cause developmental and other health problems that may arise later in life remains unknown, as few children born through PGS have reached puberty.

Some of the risks associated with PGS may also be psychological. The President's Council on Bioethics expressed concern that even "the present, more modest, applications of PGD – screening for severe medical conditions, screening for genetic predispositions for a given disease, elective sex selection, and selection with an eye to creating a matching tissue donor" treat the child as merely a "means to the parents' ends."¹¹² Under this view, embryo selection based on genetic traits establishes the child as an instrument of the parents' goals, as opposed to a gift in and of himself or herself. Jurgen Habermas and Michael Sandel have argued that this level of parental control limits the sense of freedom and personal control children born through PGS will have over their lives.¹¹³ However, in the absence of PGS, many parents exercise extensive control over

109. Mastenbroek et al., *supra* note 16, at 15-17; Verlinsky et al., *supra* note 28, at 292-94; *Preimplantation Genetic Diagnosis Okay for Test-Tube Babies, Study Finds*, SCIENCE DAILY, June 18, 2007, <http://www.sciencedaily.com/releases/2007/06/070616191628.htm>.

110. Mastenbroek et al., *supra* note 16. For further explanation, see *supra* note 37.

111. Munné et al., *supra* note 37.

112. PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 95 (2004), *available at* http://www.bioethics.gov/reports/reproductionandresponsibility/_pcbe_final_reproduction_and_responsibility.pdf [hereinafter PRESIDENT'S COUNCIL].

113. JURGEN HABERMAS, *THE FUTURE OF HUMAN NATURE* 75 (2003); MICHAEL J. SANDEL, *THE CASE AGAINST PERFECTION* 82-83 (2007).

their children's lives and use their children as instruments of their own ends. Psychological research is needed to substantiate the view that PGS would significantly increase this risk.

While continued research is necessary to better understand the health implications of PGS for offspring, the government should make efforts in the present to educate physicians and prospective parents on the known risks to offspring from IVF and the potential risks associated with embryo biopsy, despite their uncertain scope and magnitude.

2. Risks to the Prospective Parents

Risks also exist for the prospective parents who engage in PGS. IVF poses several health risks to women. The hormone stimulation procedures required to retrieve the eggs can lead to ovarian hyperstimulation, which can result in nausea, vomiting, shortness of breath, distended abdomen, and hospitalization.¹¹⁴ The multiple gestations common with IVF also increase maternal risks, such as pregnancy-induced hypertension, gestational diabetes, and excessive bleeding in labor and delivery.¹¹⁵ IVF also doubles the risk of an ectopic pregnancy, which can necessitate surgery and in rare cases result in death.¹¹⁶ Serious concern also exists about the long-term risks associated with IVF.¹¹⁷ Some researchers hypothesize that the hormones included in the ovarian stimulation injections may increase the risk of breast, ovarian, and endometrial cancer.¹¹⁸ However, to date research has found no association between these cancers and IVF use, but more studies should be performed in the future to confirm these early findings.¹¹⁹

114. See WORKSHOP REPORT, *supra* note 59, at 17-19; Grainger, Fraizer & Rowland, *supra* note 59, at S162.

115. See, e.g., Barbara Luke & Morton B. Brown, *Contemporary Risks of Maternal Morbidity and Adverse Outcomes with Increasing Maternal Age and Plurality*, 88 FERTILITY & STERILITY 283, 286 (2007). For instance, the risk of pregnancy-induced hypertension doubles from just under 4% in women pregnant with one fetus to just under 8% in those carrying twins and over 11% in those carrying triplets. *Id.*

116. Willem M. Ankum, *Diagnosing Suspected Ectopic Pregnancy*, 321 BRIT. MED. J. 1235, 1235 (2000) (stating that the maternal death rate associated with ectopic pregnancies is estimated to be 0.3-0.4 per 1000 ectopic pregnancies); Ctrs. for Disease Control & Prevention, *Ectopic Pregnancy—United States, 1990-1992*, 27 MORBIDITY & MORTALITY WKLY. REP. 44, 46-48 (1995) (finding 19.7 ectopic pregnancies out of 1000); Soini et al., *supra* note 93, at 606 (finding IVF pregnancies had a 4% chance of being ectopic); Stephen K. Van Den Eeden et al., *Ectopic Pregnancy Rate and Treatment Utilization in a Large Managed Care Organization*, 105 OBSTETRICS & GYNECOLOGY 1052, 1052 (2005) (finding a rate of 20.7 ectopic pregnancies per 1000).

117. WORKSHOP REPORT, *supra* note 59, at 22.

118. *Id.* at 22-24.

119. *Id.* at 24-26.

Clinicians and policymakers frequently overlook the risks to women from engaging in ART because the women are often willing to accept almost any personal risk to have a healthy child. Due to the vulnerability of the ART patient population, the government in conjunction with physicians should develop practice guidelines designed to reduce the risk of ART. The government should also help ensure that clinicians inform women of the risks and benefits associated with IVF, as well as alternatives, such as natural IVF and mild IVF, that may mitigate these risks.¹²⁰

In addition to determining the risks to the offspring and the mother, prospective parents should also consider two additional factors that may impact the benefit of making a particular genetic selection: the accuracy of the genetic tests and the complex risk factors associated with embryo selection.¹²¹ Inaccurate genetic tests can produce false positives or false negatives, thereby negating the benefit of the selection.¹²² Certain features of embryo selection may also result in parents' selecting for a specific trait and inadvertently also selecting for an undesired trait. Both factors can easily result in a miscalculation of the benefit gained by undergoing PGS.

The potential for genetic testing errors creates risk within PGS. These errors can arise from the limited genetic sample available for PGS, inaccuracy of the tests themselves, and human laboratory errors. Despite public beliefs to the contrary, the government conducts very little oversight or regulation of genetic tests in comparison to other healthcare products.¹²³ The FDA has not approved

120. Natural IVF, which does not use hormone injections to stimulate the ovaries, but removes only one egg as the woman ovulates, eliminates the need for stimulation hormones altogether. For other women who need ovarian stimulation, clinicians have started to successfully use milder doses of hormones to reduce the negative side effects for women, the costs of IVF, and the risk of pharmaceutical interference with embryo development. F. Ubaldi et al., *Hopes and Facts About Mild Ovarian Stimulation*, 14 REPROD. BIOMEDICINE ONLINE 675, 679 (2007).

121. The risks associated with misdiagnosis and embryo selection are risks to the parents as opposed to risks to the children born through PGS because any child born as a result of these errors could not have been born in their absence. A misdiagnosis that caused parents to select an affected embryo over a non-affected embryo could not be said to have harmed the resultant child, as that child would not otherwise been born. See PARFIT, *supra* note 94, at 356-61 (arguing that such an action cannot be said to harm the resultant child because a different person would have been born had the error not occurred); Robertson, *supra* note 105, at 27 (arguing that "if enabling the birth of children with diseases such as cystic fibrosis, Tay-Sachs, deafness, sickle cell anemia, or Huntington's disease is ethically problematic, it would have to be on some ground other than harm to the children themselves").

122. BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 4.

123. Genetics & Pub. Policy Ctr., Genetic Testing Quality Initiative, <http://www.dnapolicy.org/policy.gt.php> (last visited Mar. 30, 2008) (noting the results of a recent study finding that the public widely believed that the government regulated the quality of genetic tests, and that the government

genetic tests as safe and effective unless they are sold commercially as test kits, which rarely occurs.¹²⁴ Laboratories conducting genetic tests are not required to go through any accreditation or approval process outside of the very basic requirements that the Clinical Laboratory Improvement Amendments of 1988 (CLIA) places on all laboratories.¹²⁵ These requirements do not address any of the specific complexities associated with genetic testing, such as penetrance, gene-gene interaction, and gene-environment interaction.¹²⁶

Devastating errors in PGS practice have occurred as a result.¹²⁷ The level of misdiagnoses in PGS remains largely unknown, but while conducting interviews with couples that had undergone PGS, members from the Genetics and Public Policy Center found that the embryos of three of seven women who had become pregnant following PGS had been misdiagnosed.¹²⁸ Due to error rates that are “not negligible,” the Preimplantation Genetic Diagnosis International Society recommends that all PGS patients undergo prenatal screening during pregnancy, either through amniocentesis or chorionic villus sampling, to confirm the diagnosis.¹²⁹ In the absence of comprehensive data collection on PGS procedures and their outcomes, the frequency and impact of misdiagnosis are impossible to calculate.¹³⁰

More so than in nearly any other area of medical testing, every effort should be made to ensure the accuracy of the tests and procedures performed for PGS. Secondary genetic tests cannot be performed to confirm results in the forty-eight hours required to implant the embryo. Extra DNA is not available if a sample is

should perform this function).

124. Gail H. Javitt, *Policy Implications of Genetic Testing: Not Just for Geneticists Anymore*, 13 ADVANCES IN CHRONIC KIDNEY DISEASE 178, 179 (2006) (stating that of the more than 900 genetic disease tests available, test kits are available for only around a dozen).

125. See Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a (2000); see also Javitt, *supra* note 124, at 178.

126. See *supra* note 19.

127. In one documented case, a couple that already had a child with Fanconi anemia underwent PGD to select an embryo that was unaffected by Fanconi anemia and was a genetic tissue match for their sick child. Instead of transferring two unaffected embryos that could serve as cord blood donors to save the existing child, laboratory error resulted in the transfer of two embryos with the Fanconi anemia genetic mutation. See, e.g., GENETICS & PUB. POLICY CTR., ISSUE BRIEF ON OVERSIGHT OF PREIMPLANTATION GENETIC DIAGNOSIS I (2006), available at http://www.dnapolicy.org/images/issuebriefpdfs/Oversight_of_PGD_Issue_Brief.pdf.

128. *Id.*

129. *The Preimplantation Genetic Diagnosis International Society (PGDIS): Guidelines for Good Practice in PGD*, 9 REPROD. BIOMEDICINE ONLINE 430, 433 (2004) (stating that “[g]iven that the error rate after single-cell analysis is not negligible, conventional prenatal diagnosis should be recommended to confirm and complete the analysis”).

130. See GENETICS & PUB. POLICY CTR., *supra* note 127, at 1.

lost, contaminated or destroyed. For parents, the risk of misdiagnosis can have extreme consequences, such as the loss of a young child to a severe genetic disorder, the loss of a potentially healthy, viable embryo, or being faced with the difficult decision of whether to carry an affected child to term.

The embryo selection process also generates uncertainties. First, even with one hundred percent accurate genetic testing, PGS may cause a couple, and quite frequently an infertile couple, to discard an embryo that would never have developed the undesired disease or condition. Not all genetic conditions are one hundred percent penetrant, meaning that having the allele associated with a disorder or condition may not always result in its physical presentation.¹³¹ Additional genetic or environmental factors that affect gene expression are often difficult to identify. Physicians and patients should consider gene penetrance in weighing the benefits of screening for a certain condition or discarding an embryo based on a specific result.

Second, our knowledge of the human genome and its functional mechanisms remains in its infancy. Prior to the completion of the human genome project, scientists estimated that the human genome contained approximately 100,000 protein-coding genes based upon the breadth of human function.¹³² Now that the project is “essentially ‘finished,’” its findings suggest that there are only 20,000 to 25,000 protein-coding genes, indicating that each gene performs substantially more functions than scientists originally thought.¹³³ Permitting parents to select for or against certain alleles based upon the first function discovered may have significant consequences, as they may unwittingly screen in certain detrimental traits or screen out certain positive traits.

This point is illustrated by sickle cell anemia, a recessive genetic disease with severe health consequences, such as severe pain episodes, strokes, anemia, kidney damage, and lung blockage.¹³⁴ In families with a high prevalence of sickle cell anemia, PGS could screen out affected and carrier embryos. Doing so may result in an evolutionary disadvantage, however, because having only one of the sickle cell alleles produces no disease, but instead provides malarial resistance.¹³⁵ While malaria is not a major health concern for many Americans, alleles linked

131. Human Genome Project, Evaluating Genetic Tests: Some Considerations, http://www.ornl.gov/sci/techresources/Human_Genome/resource/testeval.shtml (last visited Mar. 30, 2008).

132. Human Genome Project, How Many Genes Are in the Human Genome?, http://www.ornl.gov/sci/techresources/Human_Genome/faq/genenumber.shtml (last visited Mar. 30, 2008).

133. *Id.*

134. Ga. Comprehensive Sickle Cell Ctr. at Grady Health Sys., The Sickle Cell Information Center, <http://www.scinfo.org/sicklept.htm> (last visited Mar. 30, 2008).

135. *Id.*

to other disorders or undesirable characteristics may confer different forms of evolutionary advantage, which could explain their continued existence in the gene pool.

Many alleles associated with desirable characteristics may also be unexpectedly associated with negative ones. For example, a couple may wish to select alleles associated with red hair and freckled skin, but will discover that this phenotype also carries a heightened risk of melanoma.¹³⁶ Obtaining more data about the range of harms and benefits associated with a certain allele will be imperative to enable people to weigh the benefits of screening out the allele against screening out a potential benefit or screening in a certain detriment.

Along with the benefit of being able to select the genetic traits of one's children comes the responsibility of taking the opportunity to choose genetic traits and choosing them correctly.¹³⁷ In a world where PGS is more common, parents may experience personal and social pressure to undergo PGS to select children based on the presence of desirable traits and to avoid the responsibility for children born with undesirable traits.¹³⁸

Government intervention could mitigate the above risks to prospective parents. Efforts to improve the safety and efficacy of PGS procedures, increase research into the long-term health risks of ART, and disseminate information on the risks and benefits of PGS could improve the practice of PGS and the ability of parents to make informed treatment decisions. Specific regulatory objectives will be discussed in Part IV.

3. Risks to Society

In addition to the risks individuals face from PGS, the government should consider the impact PGS could have on society as a whole. As use of the technology increases and the range of genetic tests performed expands, the effects of PGS will no longer be limited to the individuals who use it or are created by it.¹³⁹ Unregulated, the widespread practice of PGS threatens to increase health disparities due to lack of access, discrimination, and tensions over the value of an embryo.

136. L.P. Fernandez et al., *MC1R: Three Novel Variants Identified in a Malignant Melanoma Association Study in the Spanish Population*, 28 *CARCINOGENESIS* 1659, 1659 (2007).

137. SANDEL, *supra* note 113, at 87.

138. *Id.* at 88-89 (noting that parents of children with Down syndrome and other genetic disabilities feel judged or blamed); PRESIDENT'S COUNCIL, *supra* note 112, at 96.

139. PRESIDENT'S COUNCIL, *supra* note 112, at 96-98.

a. Access and Health Disparities

Access to ART, including PGS, is limited both financially and culturally.¹⁴⁰ Financially, PGS is already out of reach for many couples. One cycle of PGS, including IVF, can cost between \$12,500 and \$16,000.¹⁴¹ While some insurance companies have provided coverage for PGD to screen out a serious genetic disorder, most companies generally do not provide coverage for PGS for infertility.¹⁴² As DNA microarrays enable parents to screen for multiple genetic conditions, the price for PGS will only increase.¹⁴³

Cultural and educational factors can also inhibit access to PGS. While income and health insurance are important factors leading to disparities in health across populations, health care researchers also argue that “much of the answer has to be found elsewhere.”¹⁴⁴ It remains important to consider that discriminatory practices,¹⁴⁵ educational inequality,¹⁴⁶ and cultural biases¹⁴⁷ also

140. Mary Crossley, *Dimensions of Equality in Regulating Assisted Reproductive Technologies*, 9 J. GENDER, RACE & JUST. 273, 278-79 (2005); Eve C. Feinberg et al., *Economics May Not Explain Hispanic Underutilization of Assisted Reproductive Technology Services*, 88 FERTILITY & STERILITY 1439 (2007); Lynn White, Julia McQuillan & Arthur L. Greil, *Explaining Disparities in Treatment Seeking: The Case of Infertility*, 85 FERTILITY & STERILITY 853, 855-56 (2006).

141. BARUCH ET AL., *supra* note 17, at 22 (estimating the cost of IVF to be \$10,000-\$12,000 and the cost of PGD to be \$2500-\$4000); Reproductive Genetics Institute, *supra* note 63 (charging up to \$5000 for PGD screening plus \$2000 for embryo biopsy and other mandatory services).

142. Crossley, *supra* note 140, at 278. Some states require some form of insurance coverage for IVF. Seven states – Arkansas, Hawaii, Illinois, Maryland, Massachusetts, New Jersey, and Rhode Island – have passed legislation mandating that insurance companies provide coverage for IVF. Three other states – Montana, Ohio and West Virginia – have laws requiring insurance companies to cover infertility treatments, but not specifically IVF. Finally, California and New York require coverage for infertility, but specifically exclude coverage for IVF. See Nat’l Conference of State Legislators, 50 State Summary of State Laws Related to Insurance Coverage for Infertility Therapy, <http://www.ncsl.org/programs/health/50infert.htm> (last visited Mar. 30, 2008). To date, no state has extended mandatory insurance coverage to PGS screening.

143. See, e.g., WORLD HEALTH ORG., GENETICS, GENOMICS AND THE PATENTING OF DNA: REVIEW OF THE POTENTIAL IMPLICATIONS FOR HEALTH IN DEVELOPING COUNTRIES 13-14 (2005), available at <http://www.who.int/genomics/FullReport.pdf> (discussing the restrictive licensing practices of Myriad Genetics and high costs of tests for the BRCA1 and BRCA2 genes, which are associated with breast, ovarian, and prostate cancer).

144. White, McQuillan & Greil, *supra* note 140, at 855; see also Feinberg et al., *supra* note 140, at 1439-41.

145. Michelle van Ryn & Jane Burke, *The Effect of Patient Race and Socio-Economic Status on Physicians’ Perceptions of Patients*, 50 SOCIAL SCI. & MED. 813, 813-17 (2000).

146. Tarun Jain & Mark D. Hornstein, *Disparities in Access to Infertility Services in a State with Mandated Insurance Coverage*, 84 FERTILITY & STERILITY 222 (2005).

147. Feinberg et al., *supra* note 140, at 1441.

create significant barriers to care. In Massachusetts, which mandates insurance coverage for IVF services, researchers found that Hispanic/Latino women used IVF significantly less than expected, based on population demographics, while Chinese and other Asian/Pacific Islanders used IVF significantly more than expected.¹⁴⁸ Some of this disparity may result from reduced access to health insurance amongst Hispanic/Latino women.¹⁴⁹ However, disparities in use by level of education were much more striking. None of the infertility patients studied had less than a high school education, compared with 15.1% of the state population.¹⁵⁰ Likewise, almost half (49.6%) of the patients had advanced degrees, compared with 12.4% in the state.¹⁵¹ Other researchers have corroborated these results by finding that among individuals in the military health care system, who have relatively equal access to care and higher education rates than the average population, Hispanics were still strongly underrepresented among ART patients despite similar levels of infertility.¹⁵²

Inequalities in access can increase both health and socioeconomic disparities. Health disparities between socio-economic groups often result in disparities in educational, occupational, and income opportunities, which can in turn further exacerbate existing inequalities.¹⁵³ Unregulated PGS use has the

148. Jain & Hornstein, *supra* note 146.

149. The Massachusetts mandate requires insurance companies that provide pregnancy coverage to also cover medically necessary infertility diagnosis and treatment, which would include IVF. MASS. GEN. LAWS ch. 175, § 47H (1998). However, the mandate does not provide access to infertility treatments to women who do not have any insurance coverage at all. Therefore, the disparity may result from a lack of insurance coverage in general amongst Latino/Hispanic women, as opposed to a reluctance to use the technology.

150. Jain & Hornstein, *supra* note 146, at 222.

151. *Id.*

152. Feinberg et al., *supra* note 140, at 1439. The authors examined the use of ART services at Walter Reed Medical Center within the military health care system, which closely resembles an equal-access-to-care model. In the Department of Defense, only 6.5% of the Hispanic population did not graduate from high school, compared with 36.4% of the general U.S. Hispanic population. Hispanics represented 9% of the Department of Defense population, but only 4% of the ART population at Walter Reed. The authors concluded that this result is “markedly less than expected if use was primarily driven by cost.” *Id.* at 1440.

153. Nancy E. Adler & Katherine Newman, *Socioeconomic Disparities in Health: Pathways and Policies*, 21 HEALTH AFF. 60 *passim* (2002). The link between disparities in socioeconomic status and disparities in health status is established in the medical literature, as is the severity of health disparities within the U.S. health care system. U.S. DEP’T HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2010: UNDERSTANDING AND IMPROVING HEALTH 2, 11-16 (2000), *available at* <http://www.healthypeople.gov/document/pdf/uih/2010uih.pdf> (identifying eliminating health disparities as one of two major goals for improving the health of the nation); Ernest Moy, Elizabeth Dayton & Carolyn M. Clancy, *Compiling the Evidence: The National Healthcare Disparities Reports*, 24 HEALTH AFF. 376, 376 (2005).

potential to increase health disparities across a number of medical conditions. Prospective parents undergoing PGS will have every incentive to screen embryos for genes linked to known health conditions. Doing so creates two health benefits: Their offspring will likely have fewer harmful genetic health conditions, and the parents will be aware of additional disease susceptibilities. This advance awareness will enable parents to better address the future needs of their child and possibly to mitigate or eliminate the effects of the genetic disease.

Since wealthier members of society already receive better health care and numerous other benefits, it is reasonable to question whether the advantages provided by PGS raise any additional cause for government intervention to alleviate health disparities. Two factors differentiate benefits provided via PGS from other health benefits derived by wealth after birth. First, all subsequent generations will benefit from selection against disease genes, disease susceptibility, or certain genetic conditions. Not only will the individual be advantaged, but this advantage will most likely extend to his or her immediate descendants. While other advantages, like wealth and opportunity, can be passed down to children, genetic selection offers this kind of advantage to a greater degree and with greater certainty. Individuals with a parent that has an autosomal dominant disorder, like Huntington's disease, have a 50% chance of developing the disease.¹⁵⁴ PGD offers parents the opportunity to minimize this worry for their children and their children's descendants.¹⁵⁵ Second, selection against diseases and disease susceptibility prior to implantation eliminates any suffering or medical treatment associated with a disorder. Often wealthy individuals can obtain better treatment or care, but many diseases are incurable. For instance, selecting against genes that have been linked to an increased risk of Alzheimer's disease¹⁵⁶ provides an advantage that cannot be obtained by any amount of money for treatment. Those lacking access to PGS will not be able to obtain these benefits. Not only will the burden of disease be placed on those least able to afford care, but it will also be placed on those least able to lobby for research and treatments. Over time, the shifts in the burden of disease will further exacerbate health disparities.

154. Individuals with an autosomal dominant disorder will have the disease if they have one allele associated with the disorder, as opposed to autosomal recessive disorders, which require individuals to have two disease alleles to have the disease. Children of individuals with autosomal dominant disorders have a 50% chance of having the disease. Medline Plus, Autosomal Dominant, <http://www.nlm.nih.gov/medlineplus/ency/article/002049.htm> (last visited Mar. 30, 2008).

155. While the children could marry an individual with Huntington's disease and then have this concern arise again, being able to eliminate the immediate risk and worry is highly valuable.

156. See Harrington et al., *supra* note 3.

b. Eugenics and the Impact on Individuals Living with Disabilities

The government should also consider whether individuals' use of PGS directly harms other members of society. In many ways, PGS is the technological manifestation of the early twentieth-century eugenicists' goal to "improve the human condition through genetic selection."¹⁵⁷ The seductive nature of this goal should not be underestimated. In the absence of genetic selection technology, more than thirty U.S. states enacted involuntary eugenic sterilization laws, which resulted in the forced sterilization of over 60,000 Americans deemed "unfit" to procreate during the twentieth century.¹⁵⁸ Although the U.S. government is unlikely to require individuals to undergo PGS, we should not ignore the argument claiming that "through ART, the genetics revolution, and carte blanche procreative liberty, we could do unto ourselves via the collective impact of individual decision-making what governments have imposed in the past in the name of bettering the human condition."¹⁵⁹

A number of legal and ethical scholars have argued that in the absence of governmental regulation and enforcement, individual eugenic practices to select desirable genetic traits, such as PGS, cease to be morally problematic.¹⁶⁰ Judith Daar has noted that in a diverse society like the United States, "concerns about eugenics must be viewed from a perspective of 'individual-relativism,'" such that "one parent's idea of a 'good birth' may be a disappointment, or worse, for another parent."¹⁶¹ Other liberal pluralists argue that while most parents will want to improve the overall health and well-being of their children, their ideas of how to do so are likely to differ significantly.¹⁶² This argument has merit in that multi-use PGS will provide parents with significantly more choice over the types of characteristics their offspring possess. In contrast to state eugenic policies of the past, individual embryo selections do not violate others' reproductive rights or

157. Malinowski, *Choosing*, *supra* note 20, at 204; *see also* Judith F. Daar, *ART and the Search for Perfectionism: On Selecting Gender, Genes and Gametes*, 9 GENDER, RACE & JUST. 241, 260-62 (2005).

158. Daar, *supra* note 157, at 261.

159. Malinowski, *Choosing*, *supra* note 20, at 204; *see also* BUCHANAN ET AL., *supra* note 79, at 177.

160. BUCHANAN ET AL., *supra* note 79, at 27-60, 156-91, 304-45; ROBERT NOZICK, ANARCHY, STATE AND UTOPIA 315 (1974); Nicholas Agar, *Liberal Eugenics*, 12 PUB. AFF. QUART. 137 (1998); Daar, *supra* note 157, at 260-66.

161. Daar, *supra* note 157, at 265, 271-72 (arguing that "both parents and children can be harmed if a parent is denied the opportunity to select to birth a child" possessing a much desired trait, such as gender).

162. This notion of liberal pluralism and autonomy has been discussed in greater depth elsewhere. *See, e.g.*, BUCHANAN ET AL., *supra* note 79, at 176-79; SANDEL, *supra* note 113, at 75-83; Agar, *supra* note 160, at 137.

personal autonomy, thereby mitigating some of the social risk associated with reproductive genetic selection.

However, the liberal eugenics argument fails to address how PGS affects the lives of individuals with the undesired conditions. In a recent survey, 81% of Americans believed that PGS could lead to further discrimination against the disabled.¹⁶³ A subsection of the disability community, known as the Expressivists, has argued that the use of preimplantation and prenatal genetic tests to select for certain traits sends a hurtful message to people with those traits.¹⁶⁴ Disability activist Marsha Saxton has commented that this message represents “the greatest insult: some of us are ‘too flawed’ in our very DNA to exist; we are unworthy of being born.”¹⁶⁵ While the desire to bring a child into the world without seriously limited capabilities does not imply a belief that individuals with those disabilities should not exist, policymakers should be aware of these concerns and be prepared to address them.¹⁶⁶

Governments seeking to address these concerns face a daunting task. Permitting parents to discard embryos with “undesirable” genetic traits and conditions without any government oversight appears to sanction overtly eugenic practices. In this vein, the President’s Council on Bioethics has argued that unregulated PGS risks “normalizing the idea that a child’s particular genetic makeup is quite properly a province of parental reproductive choice, or the idea that entrance into the world depends on meeting certain genetic criteria.”¹⁶⁷ Alternatively, Adrienne Asch has spoken out against any regulatory attempt at delineating which genetic tests are appropriate for physicians to offer for reproductive purposes.¹⁶⁸ By permitting individuals to select against some traits, but refusing to let people select against other traits, Asch argues that the

163. ANDREA KALFOGLOU ET AL., GENETICS & PUB. POLICY CTR., REPRODUCTIVE GENETIC TESTING: WHAT AMERICA THINKS 36 fig. 6.1 (2004), *available at* <http://www.dnapolicy.org/images/reportpdfs/ReproGenTestAmericaThinks.pdf> (surveying a nationally representative sample of 4834 Americans).

164. Erik Parens & Adrienne Asch, *The Disability Rights Critique of Prenatal Genetic Testing: Reflections and Recommendations*, in PRENATAL TESTING AND DISABILITY RIGHTS 3, 13-14 (Erik Parens & Adrienne Asch eds., 2000). Adrienne Asch has specified that the message offends because it permits a single trait to stand in for the whole person, and in doing so, implies that it is unnecessary to learn about the rest of that individual. *Id.* at 13 (citing Adrienne Asch, *Why I Haven’t Changed My Mind About Prenatal Diagnosis: Reflections and Refinements*, in PRENATAL TESTING AND DISABILITY RIGHTS 234, 235-36 (Erik Parens & Adrienne Asch, eds., 2000)).

165. Marsha Saxton, *Disability Rights and Selective Abortion*, in ABORTION WARS: A HALF CENTURY STRUGGLE, 1950-2000, at 391 (Rickie Solinger ed., 1998).

166. BUCHANAN ET AL., *supra* note 79, at 274.

167. PRESIDENT’S COUNCIL, *supra* note 112, at 95.

168. Adrienne Asch, *Disability Equality and Prenatal Testing: Contradictory or Compatible?*, 30 FLA. ST. U. L. REV. 315, 338-39 (2003).

government makes a determination that some lives are valued and some lives are not, which “will surely exacerbate the discrimination and stigmatization of future children with the listed conditions.”¹⁶⁹ However, passing regulation to limit the use of PGS to certain disorders and traits does not necessitate the inference that the government does not value the lives of its existing citizens with those disorders.¹⁷⁰ Regulation to ensure resources and protection for individuals with disabilities should accompany regulation for PGS.

Governments that have examined issues relating to eugenics and discrimination arising from PGS have taken a range of approaches. Germany,¹⁷¹ Switzerland,¹⁷² Austria,¹⁷³ and Italy¹⁷⁴ have all passed legislation banning the practice of PGS entirely, ostensibly to avoid any implications of eugenic practices. Countries like Canada¹⁷⁵ and the United Kingdom¹⁷⁶ have established administrative agencies to review and regulate PGS. The Japanese government has not passed legislation limiting PGS, but the Japanese Society of Obstetricians and Gynecologists enacted a strict licensing system that carefully considers the potential effect of a specific use of PGS on disabled members of society before permitting a clinic to use PGS for that indication.¹⁷⁷ To date, use of PGS has been extremely limited in Japan.¹⁷⁸

The U.S. government should not ignore the ability of thousands of individual reproductive decisions to increase discrimination against individuals with

169. *Id.* at 339.

170. BUCHANAN ET AL., *supra* note 79, at 278.

171. Gesetz zum Schutz von Embryonen [Act for Protection of Embryos], Dec. 19, 1990, BGBl. I, 69 at 2746 (F.R.G); *see also* Henning M. Beier & Jacques O. Beckman, *German Embryo Protection Act (October 24, 1990)*, 6 HUM. REPROD. 605, 605-06 (1991).

172. Bundesgesetz über die medizinisch unterstützte Fortpflanzung [FMedG] [Federal Law on Assisted Reproduction] Dec. 18, 1998, Die Bundesversammlung der Schweizerischen Eidgenossenschaft, art. 24, 1-2 (Switz.); *see also* Bartha M. Knoppers & Rosario M. Isasi, *Regulatory Approaches to Reproductive Genetic Testing*, 19 HUM. REPROD. 2695, 2695 (2004).

173. Gentechnikgesetz – GTG und Änderung des Produkthaftungsgesetzes [The Austrian Gene Technology Act] Bundesgesetzblatt [BGBl] No. 510/1994 (Austria); *see also* Knoppers & Isasi, *supra* note 172, at 2695.

174. Norme in materia di Procreazione Medicalmente Assistita [Medically Assisted Reproduction Law]. Racc. Uff., Presidential Decree, Feb. 19, 2004, Feb. 24, 2004, No. 4 (Italy).

175. Assisted Human Reproduction Act, 2004 S.C. ch. 2 (Can.) (establishing Assisted Human Reproduction Canada (AHRC) a federal regulatory agency to oversee the use of AHR in Canada); *see also* Health Canada, Assisted Human Reproduction Canada, www.hc-sc.gc.ca/hl-vs/reprod/agenc/index_e.html (last visited Mar. 30, 2008).

176. Human Fertilisation and Embryology Act, 1990, c. 37, § 5 (U.K.).

177. *See* M. Sugiura-Ogasawara, *Reply to: Preimplantation Genetic Diagnosis for Translocations*, 21 HUM. REPROD. 840 (2006).

178. *See* Santiago Munné, *Preimplantation Diagnosis for Translocation*, 21 HUM. REPROD. 839 (2006).

negatively perceived genetic conditions. While the Americans with Disabilities Act¹⁷⁹ and the Civil Rights Act¹⁸⁰ provide legal protection for some individuals that may face increased discrimination as a result of widespread PGS use, future advances in genetic testing may result in discrimination against many other individuals with unprotected conditions or characteristics, such as sexual preference.¹⁸¹ In instances where there is direct evidence of harm to a population, and where anti-discrimination laws are absent or inadequate to reduce the discriminatory impact, the government should limit parents' ability to use PGS for the related condition.

c. Respecting and Protecting Potential Human Life

The government should also consider the sentiments of those individuals who will be outraged by any procedure that permits prospective parents to discard embryos. Many religious individuals oppose the use of IVF and PGS for any purpose.¹⁸² As the reasons for discarding embryos become less about avoiding severe disorders or infertility and more about selecting for desirable genetic characteristics, many other members of the population may join the opposition.¹⁸³ This opposition may stem in part from the belief that discarding embryos for treatable medical conditions, disorders with mild symptoms, and non-medical traits does not account for the embryos' moral worth.¹⁸⁴

In *Gonzales v. Carhart*, the Supreme Court recently reaffirmed the state's ability to regulate reproductive medicine in an effort to express its "profound

179. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327 (codified at 42 U.S.C. §§ 12101-12213 (2000)).

180. Civil Rights Act of 1964, Pub. L. No. 88-352, 78 Stat. 241 (codified as amended in scattered sections of 5, 28, 42 U.S.C.).

181. Americans with Disabilities Act of 1990, Pub. L. No. 101-336, 104 Stat. 327, 376 (codified at 42 U.S.C. § 12211 (2000)) (specifically stating that "homosexuality and bisexuality are not impairments and as such are not disabilities"); *Desantis v. Pacific Tel. & Tel.*, 608 F.2d 327 (9th Cir. 1979) (holding generally that Title VII of the Civil Rights Act did not prohibit discrimination on the basis of sexual orientation); see also Pekka Santtila et al., *Potential for Homosexual Response Is Prevalent and Genetic*, 77 BIOLOGICAL PSYCHOL. 102, 102-05 (2008).

182. See, e.g., Mo Wolterling, *The Clone Wars: Have We Surrendered Donum Vitae?*, SEQUELA, www.rc.net/org/humanfamily/clonewars.html (last visited Mar. 30, 2008) (arguing against the use of IVF for any purpose).

183. KALFOGLOU ET AL., *supra* note 163, at 27 (finding that individuals' approval of PGD use decreased as the severity of the conditions involved moved from fatal childhood disorders to selection of traits).

184. *Id.* at 26-27 (finding that individuals' approval of PGD for less severe genetic conditions was somewhat, but not entirely related to their belief in the moral status of the embryo, and that many people gave the embryo an "intermediate" status between person and non-person).

respect for the life of the unborn.”¹⁸⁵ The Court granted the state the right to promote respect for fetal life both before and after viability.¹⁸⁶ The Court based this finding, however, on the notion that “a fetus is a living organism while in the womb, whether or not it is viable outside the womb.”¹⁸⁷ In *Planned Parenthood of Southeastern Pennsylvania v. Casey*, the Supreme Court held that the state could “from the outset . . . show its concern for the life of the unborn.”¹⁸⁸ While it has not been settled that the government’s interest in protecting the unborn extends to embryos outside a mother’s body, given the language in *Carhart* and *Casey*, and the prohibition on federal funding for embryo research, the government’s ability to restrict some uses of PGS in an effort to demonstrate respect for the unborn seems probable enough to warrant further consideration.¹⁸⁹

The question is how to weigh society’s interests in the life of the unborn against the interests of the prospective parents. In examining similar questions relating to embryo experimentation while on the Human Embryo Research Panel, Alta Charo recommended that the interests of those opposed to embryo research on moral grounds be considered in terms of the harm directly caused to them by embryo research.¹⁹⁰ Such an approach can be used to weigh societal objections to PGS based on the status of the embryo. The government should consider the following: 1) How strongly felt are the objections?; 2) Does the practice cause any form of physical, financial or emotional harm to the individuals?; 3) Are there structural obstacles that prevent individuals opposing the use from politically expressing their views?; and 4) Would their opposition deny constitutional or international human rights to others?¹⁹¹ Since individuals opposing IVF and PGS will not be forced to engage in or conduct the procedures, their harms will be limited. This analysis would grant little weight to third-party interests when compared with using PGS to select against a serious disorder, but in cases of negligible parental benefit in selecting for a particular gene, such as eye or hair color, strong public opposition may warrant government restriction of the procedure on grounds that the practice of discarding embryos for less significant reasons harms others in society. Such an analysis protects individual reproductive autonomy, but acknowledges the moral opposition to embryo destruction in instances where an individual uses PGS to screen out traits that do

185. *Gonzales v. Carhart*, 127 S. Ct. 1610, 1615 (2007) (quoting *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 877 (1992)).

186. *Id.* at 1627.

187. *Id.*

188. *Casey*, 505 U.S. at 869.

189. A more complete explication of the constitutional limitations on regulation of PGS will be provided in Part III.

190. See R. Alta Charo, *The Hunting of the Snark: The Moral Status of Embryos, Right-to-Lifers, and Third World Women*, 6 STAN. L. & POL’Y REV. 11, 20-21 (1995).

191. *Id.* at 21.

not trigger reproductive liberty protections. While establishing the right balance between reproductive liberty and moral opposition to embryo destruction will remain a thorny area of law, attempting to negotiate a middle ground will prove safer than a laissez faire approach and more palatable than a highly precautionary approach.

While recent advances in ART pose significant regulatory challenges, the risks to both individuals and society are sufficiently credible to require government intervention. As discussed above, governments in most of the developed world have heavily regulated ART, including PGS and PGD.¹⁹² In contrast, federal and state governments in the United States have neglected to regulate PGS.

C. Why Has the United States Not Regulated PGS?

One of the main reasons the United States has not regulated PGS is because American politicians do not find it politically advantageous. The lack of political interest has occurred for three reasons: 1) few studies have demonstrated harm to children from PGS; 2) the current technological limitations of PGS have restricted both patient demand and the frequency of its use for controversial purposes; and 3) PGS regulation is politically divisive. As a result, politicians have effectively tabled the issue until a significant harm or risk demands political action.

Scientific research is just beginning to reveal some of the health risks associated with IVF and PGS. This research is time-consuming, and funding is scarce. Examining the health outcomes of children born via ART requires gathering data before the pregnancy and through many years into childhood. To determine the long-term risks, studies will need to continue from before pregnancy well into adulthood.

Another difficulty is that, since the 1970s, the federal government has either greatly limited or banned the use of federal funds for embryo and fetal research.¹⁹³ The Dickey-Wicker Amendment currently prevents the use of federal funds for any activity that involves “the creation of a human embryo or embryos for research purposes; or . . . research in which human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater

192. See Knoppers & Isasi, *supra* note 172, at 2695.

193. PRESIDENT’S COUNCIL, *supra* note 112, at 127-31. The restrictions began with a prohibition on using federal funds to conduct research on IVF without approval from the Ethics Advisory Board (EAB). In 1979, the EAB attempted to authorize IVF research under certain conditions, but its recommendation was not accepted by the Department of Health, Education and Welfare. The EAB was disbanded shortly thereafter in 1980, leaving a de facto moratorium on the use of federal funds for IVF research. *Id.* at 127-28.

than that allowed for research on fetuses in utero under 45 [C.F.R. § 46.208(a)(2) or 42 U.S.C. [§] 289g(b)].¹⁹⁴ Since PGS research entails the possibility of injuring, destroying, and discarding human embryos, it will likely run afoul of the Dickey-Wicker Amendment.¹⁹⁵

The absence of federal research funding has pushed reproductive genetics out of the laboratory and into medical practice. Advances in reproductive technology, such as PGS, have been widely achieved on the basis of theory-driven rather than data-driven hypotheses,¹⁹⁶ given the lack of funds for research and the absence of legislation that requires safety and efficacy research prior to clinical use. As a result, couples often have to make treatment decisions with little evidence of safety and efficacy, and policymakers have little data to suggest a need for regulation.

The lack of PGS oversight is also due in part to the relative seriousness of current PGS indications and the small number of procedures performed each year. The small patient population and the current limitations of the technology largely have tempered concerns that PGS might be used by many people to screen for a wide range of medical and non-medical conditions. John A. Robertson, one of the field's most prominent legal scholars, has argued that it is "highly unlikely that many traits would be controlled by genes that could be easily tested in embryos"¹⁹⁷ due to the fact that most genetic conditions result from interactions between multiple genes and between the genes and the environment. Leading scientists, policymakers, and scholars have echoed Robertson's sentiment that the technological limitations associated with PGD will prevent the dystopias predicted by many ethicists and science fiction authors related to "designer babies."¹⁹⁸ Armed with reassurance that PGS is likely to have little social impact, politicians have remained reluctant to act. This view ignores the ability of recent technological advances to expand the power of PGS to screen for numerous genetic loci at one time.

Finally, politicians have been especially hesitant to consider regulating PGS because it requires consideration of the status of the embryo. Given the extreme divide in the United States regarding abortion, reaching consensus on the status

194. Balanced Budget Repayment Act of 1996, Pub. L. No. 104-99 sec. 128, 110 Stat. 26, 34.

195. Jacques Cohen & Santiago Munné, *Letter to the Editor*, 20 HUM. REPROD. 2363, 2364 (2005) (stating that evidence suggests that removing two cells from cleaved embryos can harm the embryo beyond repair).

196. John A. Collins, *Preimplantation Genetic Screening in Older Mothers*, 357 NEW ENG. J. MED. 61, 61-62 (2007).

197. John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 466 (2003).

198. PRESIDENT'S COUNCIL, *supra* note 112, at 94-97 (2004); see also FRANCIS FUKUYAMA, *OUR POSTHUMAN FUTURE: CONSEQUENCES OF THE BIOTECHNOLOGY REVOLUTION* 4-10 (2002) (describing the dystopia of future PGS use).

of the embryo appears impossible.¹⁹⁹ Political debate over embryo creation and destruction often causes people to retreat to their firmly entrenched positions on abortion, which contributes significantly to the regulatory stalemate with respect to ART in the United States.²⁰⁰

Despite this reluctance on the part of politicians, the government no longer has the luxury of delaying consideration of regulation and oversight.²⁰¹ PGS will soon offer parents the opportunity to screen embryos for hundreds of genetic and chromosomal characteristics. The development of PGS will expand the demand for the procedure and its use for controversial ends, in turn creating new individual and social risks.²⁰² The government should put in the political infrastructure to balance the potential benefits to parents of unrestricted use against the probability and severity of the risks associated with PGS.

III. WHO SHOULD OVERSEE PGS?

Once the government decides that regulation is appropriate, the next challenge is to determine who should regulate. Deciding what type of body should oversee PGS helps to determine the scope and strength of the possible oversight. In the last five years, medical, legal, and ethical scholars have proposed that a variety of entities oversee ART and PGS, including 1) professional societies, 2) state agencies, 3) existing federal agencies, or 4) a new federal agency.²⁰³ While oversight by each of these entities has benefits, the

199. See Charo, *supra* note 190, at 27 (describing the search for consensus on the status of the embryo as being “as doomed as the hunting of the illusive snark”).

200. The difficulty of passing legislation relating to ART and the appropriate uses of embryos is exemplified by the failure of Congress to pass a bill prohibiting reproductive cloning, despite general consensus that it should be illegal. See FUKUYAMA & FURGER, *supra* note 20, at 129-31, 243 (2006) (chronicling the numerous failed attempts to pass a prohibition on human cloning in the House and Senate). While the Human Cloning Prohibition Acts of 2001 and 2003 both passed the House, no prohibition on cloning has passed the Senate. See Human Cloning Prohibition Act, H.R. 534, 108th Cong. (2003); Human Cloning Prohibition Act, H.R. 2505, 107th Cong. (2001). To date, no federal prohibition on reproductive cloning exists.

201. See Malinowski, *Choosing*, *supra* note 20, at 205 (“Arguably, there is a moral imperative to not assume the luxury of time.”).

202. Cf. Mastenbroek, *supra* note 16, at 13 (demonstrating that PGS use was associated with reduced rates of ongoing pregnancy in women of advanced maternal age when compared to traditional IVF alone). While the findings of Mastenbroek et al. may reduce the immediate demand for PGS among women of advanced maternal age, many of the reasons the team suggested for the difference in rates of ongoing pregnancy resulted from technological limitations, which may be overcome. *Id.* at 16. In addition, other researchers have challenged these findings due to the study’s low embryo biopsy success rates. See *PGD Pioneers*, *supra* note 37.

203. See, e.g., FUKUYAMA & FURGER, *supra* note 20, at 14-23 (proposing an independent federal agency to address human biotechnologies and ART); Malinowski, *A Law-Policy Proposal*, *supra*

creation of a new federal agency to license and monitor ART practice is the most promising approach.

A. Professional Societies

Medical and professional societies, such as the American Society of Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART), offer one avenue for oversight of PGS.²⁰⁴ These organizations, formed by members from a particular medical field or specialty, typically offer educational services for members and develop guidelines on appropriate clinical practice.²⁰⁵ Some consider professional societies to be capable of providing “more nuanced oversight” than would be possible through legislation.²⁰⁶ Moreover, some health care providers who oppose government interference have argued that choices regarding reproductive technologies should remain a joint matter for doctors and patients.²⁰⁷

SART is the primary professional society for physicians that perform ART.²⁰⁸ It performs four main functions to assist its members – data collection and dissemination, development of practice guidelines and recommendations,

note 20, at 566 (arguing that the United States should create a regulatory system based on existing federal regulatory schemes); Noah, *supra* note 20, at 607 (suggesting that the FDA might consider reviewing their approval of fertility drugs); Norton, *supra* note 20, at 1642-50 (suggesting that Congress and state legislatures should ban nontherapeutic PGS); Parens & Knowles, *supra* note 20, at S18-21 (suggesting the creation of a federal Reprogenetics Technologies Board similar to the United Kingdom’s HFEA); Rosato, *supra* note 20, at 79-95 (proposing a “double-decker” approach to state and federal ART regulation); Joe Leigh Simpson, Robert W. Rebar & Sandra Ann Carson, *Professional Self-Regulation for Preimplantation Genetic Diagnosis: Experience of the American Society for Reproductive Medicine and Other Professional Societies*, 85 FERTILITY & STERILITY 1653 (2006) (supporting professional society regulation); *Model Assisted Reproductive Technology Act*, 9 J. GENDER, RACE & JUST. 55 (2005-2006) (proposing that states oversee the practice of ART).

204. See Simpson, Rebar & Carson, *supra* note 203, at 1653 (listing ASRM, SART, the American College of Obstetricians and Gynecologists, the American College of Medical Geneticists, the European Society of Human Reproduction and Embryology, and the Preimplantation Genetic Diagnosis International Society as professional societies that have a stake in the regulation of PGS).

205. BARUCH ET AL., *supra* note 17, at 9. For a list of ASRM and SART guidelines and practice standards issued on ART, see Malinowski, *Choosing*, *supra* note 20, at 185-87.

206. See Simpson, Rebar & Carson, *supra* note 203, at 1653.

207. Andrea L. Kalfoglou et al., *Opinions About New Reproductive Genetic Technologies: Hopes and Fears for Our Genetic Futures*, 83 FERTILITY & STERILITY 1612, 1612 (2005).

208. See Soc’y for Assisted Reprod. Tech., Welcome to SART, <http://www.sart.org> (last visited Mar. 30, 2008).

governmental interaction, and quality assurance within ART.²⁰⁹ SART requires its members to have their embryo laboratories accredited and submit data on annual success rates to the Centers for Disease Control and Prevention (CDC) in accordance with the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA).²¹⁰ ASRM is closely affiliated with SART and performs many of the same political and advisory functions, but also has members that focus on other types of reproductive medicine.²¹¹

While medical societies currently play a lead role in ART oversight,²¹² their ability to monitor, evaluate, and regulate PGS is insufficient to protect vulnerable groups from harm.²¹³ The practice guidelines issued by medical societies are voluntary and unenforceable.²¹⁴ Medical societies do not have the ability to prosecute members for non-compliance; all they can do is revoke a clinic's membership.²¹⁵ SART membership is not required to operate an ART clinic or to provide PGS. Given the substantial demand for ART services, the threat of membership loss has not served as a sufficient deterrent to force compliance with guidelines.²¹⁶ Despite ASRM's Ethics Committee's strong recommendations against using PGS solely for the purposes of non-medical sex selection,²¹⁷ the Genetics and Public Policy Center survey found that 39% of clinics were willing to provide non-medical sex selection in the absence of another reason to undergo PGS, and just under 10% of the PGS procedures performed in the surveyed clinics were for non-medical sex selection.²¹⁸ As the market for PGS expands and

209. See Soc'y for Assisted Reprod. Tech., What is SART?, <http://www.sart.org/WhatIsSART.html> (last visited Mar. 30, 2008).

210. *Id.*; see also Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. § 263a-1 to 263a-7 (2000)).

211. See Am. Soc'y for Reprod. Med., <http://www.asrm.org> (last visited Mar. 30, 2008). ASRM also publishes the journal *Fertility & Sterility*.

212. See Simpson, Rebar & Carson, *supra* note 203, at 1653 (noting that the FSRCA bill's reporting requirements are fulfilled by the ASRM, SART, and the CDC).

213. See generally BARUCH ET AL., *supra* note 17, at 9; Malinowski, *Choosing*, *supra* note 20, at 125; Noah, *supra* note 20, at 606; Parens & Knowles, *supra* note 20, at S1-25. But see David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 78 FERTILITY & STERILITY 932, 938 (2002) (stating that professional societies and individuals involved with ART have worked with one another and federal and state governments to develop an improved process that should insure higher quality care, protect the public interest, and create public confidence in ART services); Simpson, Rebar & Carson, *supra* note 203, at 1653 (arguing that self-regulation is the most appropriate policy in the United States).

214. BARUCH ET AL., *supra* note 17, at 9-10.

215. *Id.*

216. Malinowski, *Choosing*, *supra* note 20, at 187.

217. Ethics Comm. of the Am. Soc'y of Reprod. Med., *Sex Selection and Preimplantation Genetic Diagnosis*, 72 FERTILITY & STERILITY 595, 598 (1999).

218. BARUCH, KAUFMAN & HUDSON., *supra* note 28, at 5. The figure of 39% (the percentage of

demand increases for certain PGS tests, the professional societies will not be able to enforce restrictions on genetic tests.

While ASRM and other professional societies are skilled at producing guidelines for proper medical care and procedures, such societies may not be best suited to address the broader social and moral implications of PGS. They have not conducted national surveys of public opinion nor engaged the public in discourse regarding PGS's potential to shape society.

A conflict of interest also hampers the credibility of professional associations in relation to PGS. Their members benefit most from practice guidelines that limit PGS just enough to prevent government regulation, but otherwise permit widespread practice. Clinicians who perform ART, PGS, and other reproductive genetic tests comprise the leadership of the professional societies and set their policies. While these individuals should have a seat at the table to discuss potential PGS regulations, they represent only a few of many stakeholders. Recent advances in PGS testing dramatically elevate the importance of public participation in developing a policy approach.

B. State and Federal Governments

Prior to examining any state or federal regulatory proposals, it is important to examine the constitutional limitations placed on government action. The Constitution constrains state and federal governments' abilities to interfere in the reproductive decisions of individuals. In designing a regulatory approach that touches reproductive decision-making, the government should not infringe the constitutionally protected privacy rights of American citizens. During the last seventy-five years, the Supreme Court has established a Fourteenth Amendment due process right granting persons the privacy to make reproductive decisions free from undue governmental interference.²¹⁹ In order to survive a Fourteenth Amendment Challenge, the government intervention must be closely tailored to a

clinics that are willing to provide non-medical sex selection in the absence of another reason for undergoing PGS) was calculated from the data in the article, which stated that 42% of 137 clinics offered PGS for non-medical sex selection and only 7% of those would only provide the procedure if there was another reason to undergo PGS.

219. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992) (reaffirming the major holding of *Roe*, but permitting the government to make laws to protect the life of the mother and to demonstrate respect for the embryo after viability); *Roe v. Wade*, 410 U.S. 113 (1973) (granting women the right to decide whether to have an abortion within the first two trimesters of pregnancy without governmental intervention); *Eisenstadt v. Baird*, 405 U.S. 438 (1972) (extending the constitutional right granted in *Griswold* to unmarried persons); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (granting constitutional privacy protection to a married couple's decision to use contraception); *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (protecting an individual's right to reproduce from unwanted government sterilization).

PREDICTING PROBABILITY

legitimate and significant state interest that outweighs the parental privacy interest.²²⁰ Fourteenth Amendment protection extends to decisions regarding “marriage, procreation, contraception, family relationships, child rearing, and education” as they involve “the most intimate and personal choices a person may make in a lifetime.”²²¹

Without question, PGS involves some of the most intimate and private issues of human life.²²² In certain instances, the decision to use PGS is highly analogous to other constitutionally protected reproductive rights.²²³ In *Skinner v. Oklahoma*, the Supreme Court recognized the right to reproduce as one of the most fundamental civil rights.²²⁴ For some infertile individuals, PGS provides the best opportunity to have a child.²²⁵ In the absence of a compelling state interest, the state should not deny infertile couples the ability to obtain fertility treatment.²²⁶

Other uses of PGS are directly linked to the decision of whether to reproduce. John Robertson has eloquently argued that a decision should fall under the sphere of protected procreative liberties if it is “centrally connected with reproductive choice” and if its use is unlikely to cause harm to others.²²⁷ From this basis, Robertson argued that if the information provided by PGS might “strongly and plausibly impact a couple’s willingness to reproduce,” PGS is sufficiently related to the decision to procreate that it should be protected.²²⁸ While this principle provides a plausible standard, Robertson applies it too broadly. He argues that the importance of a genetic selection should rest “within a broad spectrum with the couple.”²²⁹ For decisions that could be rationally related to reproductive goals, Robertson argues that the decision to use PGS

220. *Casey*, 505 U.S. at 838; *Zablocki v. Redhail*, 434 U.S. 374 (1978) (holding that when a “statutory classification significantly interferes with the exercise of a fundamental right it cannot be upheld unless it is supported by *sufficiently important state interests and is closely tailored to effectuate those interests*” (emphasis added)); see also Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2805-08 (2005).

221. *Casey*, 505 U.S. at 851.

222. PRESIDENT’S COUNCIL, *supra* note 112, at 10.

223. Robertson, *supra* note 105, at 20-21.

224. *Skinner*, 316 U.S. at 536.

225. See, e.g., Munné et al., *supra* note 37, at 331 (finding that in a sample of 301 patients with a history of recurrent miscarriage, patients had lost 87% of their pregnancies before PGD compared to losing only 16.7% after using PGD); Verlinsky et al., *supra* note 34, at 219.

226. Robertson, *supra* note 105, at 20-21. Infertility does not create a positive right to ART, such that the government must secure and pay for treatment, only a negative right that the government must not prevent couples from attempting to have a child.

227. Robertson, *supra* note 197, at 455.

228. *Id.* at 456-57, 460-68.

229. *Id.* at 465.

should demonstrate sufficient importance to the couple to warrant protection.²³⁰ Such an interpretation would provide constitutional protection for parents to use PGS to screen for nearly any genetic condition.²³¹

The Supreme Court's recent decision in *Gonzales v. Carhart* places Robertson's analysis of the breadth of parental autonomy into question.²³² The Court held that "[w]here it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession in order to promote respect for life, including life of the unborn."²³³

As noted above, the language in *Carhart* and *Casey* may open the door for the government to extend its interest in the unborn to all embryos, even those outside the uterus.²³⁴ In that case the government could enact policies to demonstrate respect for preimplantation embryos created through IVF and PGS. Under current IVF practice, parents are at liberty to discard morphologically unsound embryos or embryos they do not intend to use. Constitutional protection for reproductive liberties should extend to the decision to discard unsound or unused embryos. To avoid the destruction of unwanted embryos, the government may seek to reduce the number of excess embryos created, but it should not be able to require a couple to undergo additional cycles of IVF just to avoid discarding embryos.

The question is whether the decision to discard embryos because one chooses not to reproduce differs fundamentally from the decision to discard embryos for specific genetic reasons through PGS. While both decisions entail discarding an embryo, the first decision necessarily involves a reproductive choice, while the other does not. Selecting one embryo over another because of a

230. *Id.* Robertson continues this analysis to argue in favor of protected selection for genes associated with gender, perfect pitch, and sexual orientation. He argues that only selection for eye color and hair color might be trivial enough to fall outside constitutional procreative liberty protections. *Id.*

231. *Id.* at 461-68.

232. *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007), upheld the Partial-Birth Abortion Ban Act of 2003, after finding that Nebraska's partial birth abortion statute violated the Constitution in *Stenberg v. Carhart*, 530 U.S. 914 (2000). The Court also held that the government may prohibit previability abortion procedures on the basis that "a fetus is a living organism while within the womb, whether or not it is viable outside the womb." *Carhart*, 127 S. Ct. at 1627.

233. *Carhart*, 127 U.S. at 1633.

234. See *infra* Subsection III.B.2; see also *Carhart*, 127 S. Ct. at 1611 (stating that the government's interest in unborn human life exists previability and postviability); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 846 (1992) (concluding that "[t]he State has legitimate interests from the outset of the pregnancy in protecting . . . the life of the fetus that may become a child").

PREDICTING PROBABILITY

preferential trait, such as eye color or hair color, does not constitute a reproductive choice that should be protected with constitutional force. For uses of PGS not deemed directly determinative of the decision to procreate, the government may be able to regulate PGS in an effort to express its respect for unborn human life by prohibiting embryos from being discarded for more “trivial” reasons.²³⁵

The recent advances in PGS further complicate this analysis because they will enable parents to select for numerous traits that may not determine the reproductive decision. Parents who would not have undergone PGS solely to select embryos based on hair or eye color, sex, or a 40% probability of having asthma, will be able to make those choices if they are initially undergoing PGS for infertility or to screen out a severe disorder. Moreover, the ability to select embryos based on the presence of a wide range of genetic traits and probabilities may determine the decision to use PGS, even in the absence of infertility or a severe disorder. Many of these choices would still reflect the overall goal of having a healthy child, but the couple’s decision to reproduce may not turn on whether they can select for many of the genetic tests available through PGS. In an unregulated market, individuals will use PGS to select for a wide range of traits because they can, not because the ability to select for each individual genetic condition shapes their decision to reproduce; thereby diminishing the parental claim to constitutional protection. In instances where the genetic test is not reasonably tied to the reproductive decision, the government will have more leeway in passing regulation. The parents’ interest in reproductive autonomy must be balanced with the competing obligations of the government to protect individuals and society from harms associated with PGS.

1. State Government

Within the above constitutional bounds, state governments could regulate PGS. The ability to govern the practice of medicine has generally been retained by the individual states, rather than ceded to the federal government.²³⁶ State governments currently run medical licensing boards, state health departments, and the general practice of medicine within each state.

Despite the states’ experience, few scholars have endorsed state regulation of ART practices.²³⁷ In seeming agreement, few individual states have sought to

235. Full explication of this issue is largely beyond the intended scope of this paper, but poses an important question for future research.

236. Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 201-02 (1999).

237. See generally Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 565-66; Noah, *supra* note 20, at 603; Parens & Knowles, *supra* note 20, at S18-21. But see Rosato, *supra* note 20, at 80-

regulate the practice of ART.²³⁸ To encourage states to do so, Congress passed FCSRCA, which required the CDC to develop a model certification program for embryo laboratories for the states to adopt voluntarily.²³⁹ The program requires states to inspect and certify embryo laboratories.²⁴⁰ To do so, the states must ensure that embryo laboratories meet and maintain the standards for consistent performance, quality assurance, record maintenance, and personnel qualifications established by the CDC.²⁴¹ To date, no state has enacted the model certification program, preferring to leave certification regulation to the federal government and professionals through FCSRCA and SART.²⁴²

State regulation faces collective action challenges. Passing legislation in all fifty states will take significant time. In contrast, if researchers uncover new individual or social harms associated with PGS, altering one federal administrative rule would be more expedient and feasible than action by fifty legislative bodies. In addition, permitting each state to regulate PGS independently will invariably lead to some states that are more lax in oversight or that do not address the practice at all. Under this scenario, the nation's PGS practices will be as permissive as the least restrictive state. Individuals who do not like the laws in their state could travel to another state with lesser restrictions and have PGS performed there, diminishing the purpose of the original statute. Finally, and most importantly, all fifty states are not well positioned to collect data and monitor the broader social impact of different uses of PGS. Examining use patterns from a national vantage point will provide much more information. A federal agency could act to initiate public discussion, centralize expertise and

95 (2004) (proposing a "double-decker" approach to state and federal ART regulation).

238. Louisiana prohibits any person from destroying a fertilized human ovum, unless that ovum fails to develop after thirty six hours. LA. REV. STAT. ANN. § 9:129 (2000); *see also* LA. REV. STAT. ANN. § 9:128 (2000) (requiring ART clinics to adhere to professional organization guidelines). Sixteen states have passed laws regarding the disposition of embryos, eggs and sperm. *See generally* Nat'l Conference of State Legislatures, State Laws on Frozen Embryos: Gamete (Egg/Sperm) and Embryo Disposition, <http://www.ncsl.org/programs/health/embryodisposition.htm> (last visited Mar. 30, 2008). Other states have passed laws relating to embryo research, which could limit PGD or PGS to the extent that it is perceived as research on the embryo. *See* 720 ILL. COMP. STAT. 510/12.1 (1993) (prohibiting research on embryos aborted for therapeutic purposes, scientific research, or laboratory experimentation); LA. REV. STAT. ANN. § 9:122 (2007) (prohibiting research on IVF embryos); ME. REV. STAT. ANN. tit. 22, § 1593 (2003) (prohibiting research on any live product of conception, intra or extra-uterine); R.I. GEN. LAWS § 11-54-1 (2002) (prohibiting any kind of experimentation on embryos before or after implantation).

239. 42 U.S.C. § 263a (2000).

240. *Id.* §§ 263a(d)(1), 263a(g).

241. *Id.* § 263a(d)(1).

242. Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 551-52. In the absence of a state program, the responsibility remains with the CDC and SART.

data collection, analyze that data for individual and social harm, and swiftly regulate harmful practices.

2. Federal Government

Regulation by the federal government could result from congressional legislation or administrative agency regulation. Regardless of the approach chosen, new legislation will be needed to regulate ART, either to expand the roles of existing agencies or to establish the authority of a new agency. In order to do any of the above, Congress must demonstrate that the regulation of ART and PGS falls under the authority granted to it by the Commerce Clause of the Constitution.²⁴³

Congress has the authority to regulate three aspects of interstate commerce: 1) the channels of interstate commerce; 2) the instrumentalities of interstate commerce and persons or things in interstate commerce; and 3) the activities that substantially affect interstate commerce.²⁴⁴ Congress previously found that reproductive clinics engage in interstate commerce when it passed the Freedom to Access Clinic Entrances Act of 1994.²⁴⁵ Subsequently, all eight circuit courts of appeals that visited this issue upheld Congress's finding as "rational."²⁴⁶ ART clinics draw staff and patients from other states and other countries.²⁴⁷ They purchase highly specialized medical supplies and equipment in interstate commerce.²⁴⁸ DNA samples must often be sent across state lines to one of a handful of genetic testing laboratories willing to perform PGS tests.²⁴⁹ These actions constitute participation in interstate commerce. In addition, in *Carhart*, which challenged the constitutionality of a federal ban on partial birth abortion, Congress's ability to regulate the practice of reproductive clinics under the

243. U.S. CONST. art. I, § 8, cl. 3.

244. *Gonzalez v. Raich*, 545 U.S. 1, 16-17 (2005) (citing *Perez v. United States*, 402 U.S. 146, 150 (1971) and *NLRB v. Jones & Laughlin Steel Corp.*, 301 U.S. 1, 37 (1937)).

245. Freedom to Access Clinic Entrances Act of 1994, Pub. L. No. 103-259, 108 Stat. 694 (codified at 18 U.S.C. § 248 (2000)).

246. *United States v. Gregg*, 226 F.3d 253 (3d Cir. 2000); *United States v. Weslin*, 156 F.3d 292 (2d Cir. 1998); *United States v. Bird*, 124 F.3d 667 (5th Cir. 1997); *Terry vs. Reno*, 101 F.3d 1412 (D.C. Cir. 1996); *United States v. Dinwiddie*, 76 F.3d 913 (8th Cir. 1996); *Am. Life League v. Reno*, 47 F.3d 642 (4th Cir. 1995); *United States v. Wilson*, 73 F.3d 675 (7th Cir. 1995); *Cheffer v. Reno*, 55 F.3d 1517 (11th Cir. 1995).

247. *See Wilson*, 73 F.3d at 680-81 (holding that there is substantial interstate travel involved in reproductive health care).

248. *See Id.* at 680; *see also Wickard v. Filburn*, 317 U.S. 111, 127-28 (1942); *United States v. Soderna*, 82 F.3d 1370, 1373 (7th Cir. 1996).

249. *See Wilson*, 73 F.3d at 680.

Commerce Clause was not before the Court.²⁵⁰ Carefully crafted legislation aimed at licensing, monitoring, and regulating the practice of ART and PGS in the United States should come within the federal government's authority granted by the Commerce Clause.

The federal government has two possible regulatory avenues for attempting to balance the interests associated with ART: direct legislation and administrative agency regulation. Legislative action is particularly ill-suited to address the concerns of a controversial and rapidly developing industry like ART. "Legislative decision-making costs are likely to be higher when conflict of interest makes it difficult to reach a collective decision and when uncertainty makes it difficult to chart a desirable course of action"²⁵¹ Reaching a legislative majority on issues surrounding appropriate use of human embryos, parental reproductive autonomy, and the perception of disability will likely prove extremely time-consuming, if not impossible.²⁵² In the meantime, the risks of unregulated ART and PGS use will go unchecked. At the rate that ART and genetics technology are developing, if legislation is passed, it will most likely be outdated by the time it is enacted. The uncertainty of risks surrounding present and future PGS practice also makes governance by legislative action especially difficult. Rather than attempting to define for all future circumstances how the law will apply or face the daunting task of amending the legislation with each new development in ART, Congress should delegate the authority to regulate ART to a specific agency and let the agency resolve the issues as they arise over time.²⁵³

Legislation aimed at expanding the mandate of an existing administrative agency or creating a new administrative agency could pass more easily by delegating controversial decisions to the expertise of the regulatory body.²⁵⁴ Agency decisions could reflect the most up-to-date scientific and sociological research on the use of PGS. A regulatory body would also have the ability to operate faster and with more freedom than legislative action. This more nimble administrative approach implemented by the federal government could take two possible forms: 1) a decentralized model with responsibilities shared among existing federal agencies, or 2) the creation of a single federal entity to license and monitor the use of ART in the United States.

250. *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007); *id.* at 1640 (Thomas, J., concurring) (noting that the parties did not challenge Congress's Commerce Clause authority in this case).

251. MURRAY J. HORN, *THE POLITICAL ECONOMY OF PUBLIC ADMINISTRATION* 14 (1995).

252. In all areas related to embryos and reproductive rights, achieving any policy that can be agreed upon by a majority is highly difficult in the United States. See FUKUYAMA & FURGER, *supra* note 20, at app. D (listing legislative activity in this field from 2001 to 2004).

253. See HORN, *supra* note 251, at 15-17.

254. See generally *id.*

a) Existing Federal Agencies

Three existing federal agencies possess authority to regulate a portion of PGS practice: the CDC, the Centers for Medicare and Medicaid Services (CMS), and the FDA. However, no agency has the jurisdiction to govern the practice of PGS as a whole, including the individual and social risks associated with the procedure.²⁵⁵ Current oversight is limited to monitoring ART program success rates, requiring general clinic sanitation and safety standards, and setting basic laboratory requirements. None of these requirements specifically address the unique aspects of IVF and PGS, including the challenges of genetic testing on a single cell's DNA, the safety and efficacy of the procedures for mothers and offspring, the ethical implications of providing PGS to screen out certain conditions, or the social implications of increased PGS use. In order to provide comprehensive oversight within existing federal agencies, Congress will either need to expand the mandate of a single agency, or expand the authority of several agencies and significantly improve their coordination.²⁵⁶

i) The Centers for Disease Control and Prevention

The CDC administers FCSRCA, the most specific regulation relating to ART in the United States.²⁵⁷ The Act requires that each ART program annually report to the CDC the “pregnancy success rates[,]. . . the identity of each embryo laboratory . . . used by such program[,], and whether the laboratory is certified . . . or has applied for such certification.”²⁵⁸ FCSRCA requires the CDC to publish this information annually, along with a list of the programs that refuse to

255. See 21 U.S.C. § 393(b)(2) (2000) (stating that the mission of the FDA is to protect the public health by ensuring that “(A) foods are safe, wholesome, sanitary, and properly labeled; (B) human and veterinary drugs are safe and effective; (C) there is reasonable assurance of the safety and effectiveness of devices intended for human use; (D) cosmetics are safe and properly labeled; and (E) public health and safety are protected from electronic product radiation”); 42 U.S.C. § 263a(b) (2000) (granting CMS the authority to require all laboratories that “solicit or accept materials derived from the human body for laboratory examination or other procedure” to receive certification); *id.* § 263a-2 (granting CDC the authority to promulgate procedures to approve accreditation organizations and States to inspect and certify embryo laboratories); Ctrs. for Disease Control & Prevention, Vision, Mission, Core Values and Pledge, <http://www.cdc.gov/about/organization/mission.htm> (last visited Mar. 31, 2008) (stating that the mission of the CDC is “[t]o promote health and quality of life by preventing and controlling disease, injury and disability”). None of these laws permit the agency to intervene into treatment decisions or consider the harms associated with a particular procedure.

256. Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 566-68.

257. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. § 263a-1 to 263a-7 (2000)).

258. 42 U.S.C. § 263a-1(a) (2000).

report.²⁵⁹ The CDC has turned over all responsibility for collecting and analyzing this information to SART.²⁶⁰ FCSRCA does not require any information on whether PGS was performed, what genetic tests were included, or whether a couple met diagnostic criteria for receiving such services.

Overall, the CDC has very limited power over ART clinics. FCSRCA specifically states that the “Secretary [of the Department of Health and Human Services] may not establish any regulation, standard or requirement which has the effect of exercising supervision or control over the practice of medicine in ART programs.”²⁶¹ The CDC does not have the power to sanction any program that does not report information.²⁶² SART, which performs inspections on behalf of the CDC, has conducted on-site inspections on less than 10% of clinics to ensure the accuracy of reporting.²⁶³ In addition, neither the CDC nor SART examines whether the clinics provide care to clinically indicated patients or abide by practice guidelines. Without the authority to regulate the practice of ART directly or the ability to mandate that all embryo laboratories receive certification, the CDC under FCSRCA has less power than a professional society.

ii) The Center for Medicaid and Medicare Services

While having no authority to regulate ART procedures, CMS can regulate the quality of genetic tests performed for PGS. Congress granted this authority to CMS through the Clinical Laboratory Improvement Act (CLIA), which regulates diagnostic tests performed in clinical laboratories.²⁶⁴ By establishing standards for laboratory testing, Congress acknowledged the importance of accurate testing to maintaining the integrity of health care. For specific areas of testing expertise, like microbiology and diagnostic immunology, CLIA grants CMS the authority to create a specialty certification. Any laboratory that performs tests in an area of specialty must become certified in that specialty by receiving a minimum score on proficiency tests and meeting specific requirements for quality assurance, quality control, and personnel.²⁶⁵ CMS has not created a specialty certification governing genetic testing laboratories.²⁶⁶ As a result, the laboratories that perform

259. *Id.* § 263a-5.

260. Adamson, *supra* note 213, at 933.

261. 42 U.S.C. § 263a-2(i)(1) (2000).

262. *Id.* § 263a-4.

263. Adamson, *supra* note 213, at 933 (stating that 30 out of 370 clinics had received on-site inspections as of 1997).

264. 42 U.S.C. § 263a(b) (2000) (requiring all laboratories that solicit or accept materials derived from the human body for laboratory examination to be certified); *see also* H. COMM. ON ENERGY AND COMMERCE, H.R. REP. NO. 100-899, *as reprinted in* 1988 U.S.C.C.A.N. 3828.

265. 42 C.F.R. §§ 493.801 to .807.

266. GAIL H. JAVITT & KATHY HUDSON, GENETICS & PUB. POLICY CTR., PUBLIC HEALTH AT

the genetic tests for PGS are not required to meet proficiency standards to ensure the accuracy of their results, nor are they required to maintain specific quality assurance and control standards specific to genetic tests. Numerous entities, including patients, directors of clinical laboratories, government advisory bodies, and non-profit organizations focused on genetics, have called for the creation of a specialty for genetic tests and heavily criticized CMS's lack of action.²⁶⁷

A specialty certification to ensure the accuracy of genetic tests is especially important for PGS. Laboratories that conduct PGS testing have extremely limited amounts of sample DNA and time to examine it. Testing protocols must be performed with speed and precision, and errors in procedure or testing reliability have dire consequences. Requiring minimum scores on proficiency tests and quality assurance measures in genetic testing laboratories will greatly improve the reliability of PGS.

iii) The Food and Drug Administration

The FDA's authority over PGS is limited because the FDA does not regulate medical procedures or drugs used in an off-label manner. The FDA does, however, have the authority to regulate any genetic test used in PGS that would qualify as a medical device.²⁶⁸ Section 201(h) of the Food, Drug and Cosmetic Act defines a device as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals."²⁶⁹ The FDA therefore has the

RISK: FAILURES IN OVERSIGHT OF GENETIC TESTING LABORATORIES 4 (2006), available at <http://www.dnapolicy.org/images/reportpdfs/PublicHealthAtRiskFinalWithCover.pdf>.

267. *Id.* at 18 (reporting that in a poll 73% of clinical laboratory directors agreed that the creation of a genetic specialty should be created); INST. OF MED., ASSESSING GENETIC RISKS: IMPLICATIONS FOR HEALTH AND SOCIAL POLICY (Lori B. Andrews et al. eds., 1994), available at http://www.nap.edu/catalog.php?record_id=2057; NAT'L INSTS. OF HEALTH, ENHANCING THE OVERSIGHT OF GENETIC TESTS: RECOMMENDATIONS OF THE SACGT (2000), available at http://www4.od.nih.gov/oba/sacgt/reports/oversight_report.pdf; SUBCOMM. MEETING ON GENETICS, CLINICAL LABORATORY IMPROVEMENT ADVISORY COMMITTEE, SUMMARY REPORT, September 10, 1997, available at <http://wwwn.cdc.gov/cliac/pdf/gsc997.pdf>; TASK FORCE ON GENETIC TESTING, NAT'L INSTS. OF HEALTH, PROMOTING SAFE AND EFFECTIVE GENETIC TESTING IN THE UNITED STATES: FINAL REPORT OF THE TASK FORCE ON GENETIC TESTING (Neil Holtzman & Michael Watson eds., 1997), available at <http://www.genome.gov/10001733>.

268. 21 U.S.C. § 321(h) (2000).

269. *Id.*; see also FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY, CLINICAL LABORATORIES, AND FDA STAFF: IN VITRO DIAGNOSTIC MULTIVARIATE INDEX ASSAYS 3 (2007), available at <http://www.fda.gov/cdrh/oivd/guidance/1610.pdf>.

ability to regulate the commercial use of any genetic test used to diagnose a preimplantation embryo with a specific genetic disease or chromosomal abnormality based on its safety and efficacy.²⁷⁰ The direct safety of genetic tests is not in question, as they are performed on cells that have already been removed from the embryo and that will be discarded.²⁷¹ However, the efficacy of the genetic tests used for PGS is indirectly linked to the safety of the test, as an inaccurate genetic test may cause parents to discard a healthy embryo or transfer an affected one. If the FDA were to regulate, the efficacy of genetic tests could be demonstrated in two ways: 1) the test must correctly and reliably identify the desired gene; and 2) the presence of that gene should reliably predict the development of the disorder.

However, the FDA has not exercised its authority to regulate the efficacy of the majority of genetic tests offered in practice.²⁷² This “hands off” approach relies heavily on voluntary laboratory compliance with current Good Manufacturing Practices, medical device reporting requirements, labeling requirements, and on CMS regulation of genetic tests through the CLIA.²⁷³ Since laboratories often create their own genetic tests rather than purchasing commercial genetic testing kits, the FDA’s reliance on CMS initially was appropriate. However, there is a need for more substantial regulation of the genetic tests used for PGS now that genetic tests are entering commercial markets in increasing numbers, microarrays can be sold to test for a panel of genetic conditions, and such tests are often accompanied by complex statistical algorithms to diagnose multiple genetic conditions.²⁷⁴

270. Interestingly, under this definition, the FDA may not have the ability to regulate the use of genetic tests to diagnose non-health related conditions. While any genetic test could be said to diagnose some form of “condition,” the context of the statute seems to suggest that the device must be used for disease or health related purposes.

271. Whether the removal of a cell from the blastocyst for genetic testing is harmful to the embryo or future offspring is a different issue than the safety of the test.

272. BARUCH, KAUFMAN & HUDSON, *supra* note 28, at 7. The FDA does regulate certain components used in in-house laboratory tests, known as analyte specific reagents (ASRs), so that healthcare providers would know how the tests were being validated. See FOOD & DRUG ADMIN., *supra* note 269, at 4 (citing 21 C.F.R. §§ 809.10(e), 809.30, 864.4020 (2007)).

273. See Sales Restriction to CLIA Regulated Laboratories that Perform High Complexity Testing, 62 Fed. Reg. 62,252 (Nov. 21, 1997) (codified at 21 C.F.R. pts. 809, 864); FOOD & DRUG ADMIN., DRAFT GUIDANCE FOR INDUSTRY AND FDA STAFF, COMMERCIALLY DISTRIBUTED ANALYTE SPECIFIC REAGENTS (ASRS): FREQUENTLY ASKED QUESTIONS 5 (2007), available at <http://www.fda.gov/cdrh/oivd/guidance/1590.pdf>.

274. Press Release, Genetics & Pub. Policy Ctr., Center Sees “New Era in Oversight” in Two New FDA Draft Guidances, Sept. 7, 2006, http://www.dnapolicy.org/news.release.php?action=detail&pressrelease_id=56.

b) New Regulatory Body

While the CDC, FDA, and CMS all have some regulatory authority over ART that could be expanded to include PGS, the range of oversight required exceeds each of their mandates.²⁷⁵ The President's Council on Bioethics stated that "the choice between delegating power to a new federal agency or to an existing agency or agencies should come down to the question of whether this arena of technology and activity raises (or is likely to raise) fundamentally new and different sorts of questions and challenges from those that have been dealt with by existing federal agencies in the past."²⁷⁶ Many of the issues associated with assisted reproduction and genetic testing raise new challenges that do not fall under the expertise of existing governmental bodies.²⁷⁷ For instance, should parents have the right to engage in non-medical sex selection? Should they be able to screen for genes associated with behavioral conditions such as shyness? What are the limits of parental discretion? What are the social implications of screening for multiple conditions? The CDC, CMS, and FDA were not designed to assess the intricate social and ethical implications of ART and genetic screening practices.²⁷⁸ Rather than straining existing agencies to expand their resources and expertise, as Michael Malinowski suggests, the government should design a new regulatory body specifically to address the scientific, legal, ethical and social challenges associated with the ever-changing world of ART.²⁷⁹

An administrative agency created to oversee the practice of ART, if designed correctly, could be centralized, flexible, and backed with legal force. Each of these factors will be important to the ability to respond adequately to the challenges of PGS and other developments in ART. Since the risks associated with PGS also include the risks associated with many of the other activities of ART practice, including IVF, ICSI, extraction and handling of gametes, and embryo creation and storage, creating an agency to regulate PGS would also provide the infrastructure necessary to oversee the entire practice of ART within one federal body. When multiple agencies have jurisdiction over an area of practice, the oversight can be disjointed. Given the uncertainty of risk associated with PGS use, the centralization of information, expertise, and regulatory authority would produce more complete oversight and improve efficiency in communication and coordination.

Centralizing information and decision-making power would also give a single regulatory body more flexibility. The flexibility to respond quickly to new

275. See PRESIDENT'S COUNCIL, *supra* note 112, at 76-78.

276. *Id.* at 189.

277. *Id.* at 187.

278. See *id.*

279. Malinowski, *A Law-Policy Proposal*, *supra* note 20, at 566.

information would enable the policy response to evolve alongside the technology. A centralized agency could quickly enjoin harmful practices or issue regulatory guidance without needing to coordinate with other federal entities.

To maintain policy continuity in an area staunchly divided by religious and political forces, the agency should be independent of the executive branch, similar to the Securities Exchange Commission.²⁸⁰ As expounded upon in greater detail by Frances Fukuyama and Franco Furger, in today's fractured political landscape, only an independent agency would have a chance of being supported by special interest groups and a majority in Congress.²⁸¹ The U.S. should not let the politics of abortion prevent it from passing important measures to regulate the future of other reproductive activities. Both sides have a great deal to gain from creating some oversight for PGS practice.²⁸² An independent agency could evaluate the benefits and risks to both individuals and society of different uses of PGS from a neutral position and establish regulations to curb unwarranted risks and promote benefits.

The creation of an independent body to monitor and regulate PGS will provide the best assurance that the risks of PGS are being considered, while the benefits of PGS continue to remain accessible.

IV. HOW SHOULD THE UNITED STATES OVERSEE THE USE OF PGS?

Designing the mandate of a new regulatory entity to oversee the use of assisted reproductive technologies, including IVF and PGS, will be challenging because of the competing interests and ethical issues involved. Instead of trying to resolve the differences between stakeholders, the government should pursue a political solution that addresses areas of overlapping stakeholder interests and balances the conflicting interests.²⁸³

The remainder of this Article argues for the creation of a new regulatory entity to oversee the practice of ART in the United States. Section IV.A identifies the major stakeholders and the factors the government should consider in policy development. Section IV.B outlines the development of policy objectives for the agency and examines possible regulatory approaches. Section IV.C proposes the creation of the Assisted Reproductive Technology Authority and outlines its initial responsibilities.

280. See FUKUYAMA & FURGER, *supra* note 20, at 293-300.

281. See *id.* at 293.

282. See *id.*

283. See Charo, *supra* note 190, at 20-23 (advocating a similar approach to addressing the conflicting interests associated with embryo research).

A. Factors To Consider

The relevant factors in developing PGS policy should reflect the interests of all stakeholders involved in the procedure or impacted by it. ART stakeholders include the individuals who want to use ART, offspring born via ART, members of society affected by its use, and ART practitioners. Their interests fall into four categories that can be used to define the mandate of a new regulatory body. The government should strive to preserve these stakeholders' interests by developing a regulatory approach that accomplishes the following goals: 1) protecting the health and well-being of individuals; 2) protecting members of society from harms caused by ART; 3) protecting individual autonomy to make reproductive decisions; and 4) protecting the interests of the medical profession. To develop a regulatory strategy, the government should rank these goals and establish an infrastructure to balance the competing interests when the goals conflict.

1. Protecting Individual Health and Well-Being

The government's highest priority should be to protect the women who undergo ART and their children, as they represent the most vulnerable entities involved in the procedure. Couples who undertake ART procedures are often willing to take disproportionate personal risks to improve their chances of having a healthy child. The children born via ART are subjected to additional risks, but they cannot consent or participate in discussions regarding the use of the procedure.

The government can protect women by improving their access to information and monitoring the clinics that provide ART services. While women should always retain the autonomy to determine what risks to accept with respect to reproductive procedures, the government can play an important role in informing their decision. Promoting or requiring genetic counseling to explain the risks of ART and PGS misdiagnosis to parents would assist them in making decisions regarding embryo selection. Efforts to fund research on women's health outcomes, ensure access to the most up-to-date health information, and provide information on other viable treatment alternatives will improve women's ability to make an informed reproductive decision.²⁸⁴ Likewise, by licensing all ART clinics and requiring them to meet minimum quality standards, the government can better assure women undergoing ART procedures of their safety.

The government can also take several actions to reduce the potential harm to

284. Women should be told that alternatives to IVF and PGD exist. For instance, they could obtain a donor egg or a surrogate carrier. AM. SOC'Y REPROD. MED., THIRD PARTY REPRODUCTION: A GUIDE FOR PATIENTS (SPERM, EGG AND EMBRYO DONATION AND SURROGACY) 3 (2006), available at <http://www.asrm.org/Patients/patientbooklets/thirdparty.pdf>.

children born through ART. Increasing research funding to monitor the health and well-being of children born through the procedures would greatly improve our understanding of the extent and magnitude of the health risks. This research would also shed light on practices within clinics, such as multiple embryo transfers, that negatively impact the overall health of ART children.

In addition to funding research, the government could seek to develop practice guidelines for assessing the risk/benefit ratio of engaging in PGS for a certain condition. Physicians should examine the benefits and the risks in a systematic manner. Numerous factors contribute to the benefit provided by the genetic selection, including 1) gene penetrance; 2) availability of treatment for the condition; 3) tolerability of the treatment; 4) efficacy of treatment; 5) impact of the disorder or characteristic on the individual; 6) the known genetic contribution to the development of the disorder; and 7) age of onset. These factors should be weighed against the known risks to children associated with IVF and PGS. Practice guidelines, while not mandated, can provide significant assistance to physicians attempting to determine which genetic selections provide sufficient benefit to outweigh the risks of PGS. Couples could also use the guidelines to make their own decisions about what types of genetic tests they should pursue.

2. Protecting Society

The government has an interest in protecting society from the potential negative effects of PGS. The collective use of PGS may result in increased health disparities and discrimination against individuals with the diseases and characteristics commonly selected against. The government also maintains an interest in demonstrating respect for potential human life.²⁸⁵

PGS impacts society less directly than the individuals engaged in the procedure; therefore, the government's interests in protecting society are less immediately relevant. However, if data begin to substantiate that PGS use will significantly increase health disparities or discrimination against disadvantaged groups, these risks should be given significant weight that in some instances could outweigh individual autonomy to use PGS. The government's interest in demonstrating respect for unborn human life should also be weighed against individual interests in using PGS in light of significant public discussion and consultation on the issue.

In order to protect society, the government should seek a regulatory strategy that enables it to identify social risks as they arise both in attitude and in practice. This will entail promoting extensive public discourse and monitoring discriminatory practices. These goals could be accomplished through notice and

285. See *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007).

comment proceedings and public hearings, monitoring the use of PGS for certain conditions, predicting future demand, and employing a diverse staff of experts to identify and raise pertinent issues. Each of these features will be especially important as the government determines whether and under what conditions parents can screen for moderate medical and non-medical conditions.

3. *Protecting Reproductive Autonomy*

Any government policy regulating ART should start from the foundation of protecting the ability of American citizens to make choices about whether to have a child through assisted reproduction and whether to implant an embryo with certain genetic characteristics. However, as noted above, constitutional protection for reproductive autonomy is not boundless.²⁸⁶ Reproductive autonomy should be granted less priority than individual and social harm because in some instances, those interests will trump an individual's right to make reproductive decisions. The government can intervene in the practice of ART and PGS without infringing on the Constitution in two instances. First, if the intervention restricts a fundamental right, it must be supported by "sufficiently important state interests and . . . closely tailored to effectuate only those interests."²⁸⁷ Second, in cases where the intervention does not restrain a fundamental right, the government may regulate so long as a rational basis exists for the regulation.²⁸⁸ If the governmental interest is important enough to outweigh an individual's privacy rights, presumably the government should act. In the absence of a fundamental right and a substantial state interest, the government should critically examine whether intervention provides the best course of action.

Decisions regarding reproduction and child-rearing remain extremely personal, even if not constitutionally protected. Parents bear responsibility for raising their children and may have a wide range of reasons for wanting to select for specific traits. In these instances, Mill's principle again becomes salient²⁸⁹ – the government should restrain itself from intervening in the decisions of citizens regarding PGS unless those decisions cause direct harm or pose a substantiated threat to others. The agency should develop a framework to balance parental interests against the individual and societal risks associated with some uses of

286. See *supra* Section III.B.

287. *Zablocki v. Redhail*, 434 U.S. 374, 388 (1978); see also *Planned Parenthood of Se. Pa. v. Casey*, 550 U.S. 832, 878 (1992) (striking a balance between the state and individual interests in reproductive decision-making as opposed to applying strict scrutiny analysis); *Carhart*, 127 S. Ct. at 1627 (affirming the balancing approach taken in *Casey*). No court has addressed whether individuals possess a constitutionally protected, fundamental right to make decisions regarding embryo selection via PGS.

288. *Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440 (1985).

289. MILL, *supra* note 81, at 73-74.

PGS. This framework should reflect the relative priority of interests and the amount of evidence supporting each interest. Maintaining this level of regulatory restraint provides credibility to the regulations that the government does institute, especially if the regulations are established in a transparent way.

4. Practitioners' Interests

In developing a regulatory strategy for PGS, the government should also consider and protect the interests of practitioners, but they should receive the lowest priority of the four stakeholder groups. Practitioners have a strong interest in enabling their patients to have healthy children and in protecting the integrity of the physician-patient relationship. Government efforts to improve access to information and ensure the quality of laboratory procedures would help promote these interests. However, practitioners are likely to view substantive regulations aimed at restricting the professional decision-making as unjust interference in the physician-patient relationship.

Practitioners are also wary of well-meaning but poorly crafted legislation that will restrict the use of PGS or result in additional burdens for the ART patient population.²⁹⁰ For instance, ART practitioners heavily criticize FCSRCA's ART registry for its unintended consequences. First, they view the registry as an unfunded mandate that pushes reporting costs on to patients or providers.²⁹¹ Second, by publishing the success rates of clinics that do report, they argue that FCSRCA might encourage clinics with low success rates to avoid reporting or to begin selectively accepting those patients most likely to become pregnant.²⁹² Patients with poorer prognoses may have difficulty accessing care. Both increases in cost and provider unwillingness to treat certain patients could further limit the population that can access ART treatment.

Many practitioners believe that legislative or governmental regulation in general will have a "chilling effect" on PGS practice as a whole in the United States.²⁹³ Since insurance carriers often do not cover PGS, couples are not financially bound to physicians or facilities. Many couples will travel to different countries in order to obtain access to the reproductive treatments they desire.²⁹⁴

290. Simpson, Rebar & Carson, *supra* note 203, at 1656-59.

291. *Id.* at 1658. While it may seem fair that those who provide and use ART pay for reporting, the providers argue that these extra costs prevent others from accessing ART.

292. *Id.* Simpson and colleagues provide a number of examples of how clinics might select healthier patients.

293. *Id.*

294. Guido Pennings, *Legal Harmonization and Reproductive Tourism in Europe*, 19 HUM. REPROD. 2689, 2690-91 (2004); Press Release, European Soc'y of Human Reprod. & Embryology, Europe Struggles To Meet the Legal, Ethical and Regulatory Challenges Posed by More Patients Traveling Abroad for PGD, July 2, 2007, <http://www.eshre.com/emc.asp?pagelId=936>.

As a result, countries with more relaxed regulations on PGS will capture more of the market, not only for patients and consumers,²⁹⁵ but also for the development of new genetic tests for predictive genomics.²⁹⁶

Not all practitioners are opposed to governmental oversight. Although some members of SART have argued that self-regulation is the “most appropriate policy in the United States,”²⁹⁷ others support the development of an independent oversight authority derived from a partnership between patients, providers, and the public.²⁹⁸ Those members supporting an independent authority advocate regulatory initiatives that include the following: “mandatory compliance, meaningful sanctions, uniformity in reporting, on-site inspection and validation, and development of practice standards, research standards, education standards, and counseling standards, as well as access to insurance coverage and research funding, and a limitation of regulation.”²⁹⁹ The backing and continued participation of ART practitioners is invaluable to any oversight proposal. Their desire for more stringent enforcement mechanisms and uniform practice standards should form the foundation of any regulatory policy.

Balancing these conflicting interests and concerns in one political initiative will be extremely challenging. However, it is imperative to establish infrastructure to address these questions as PGS technology develops.

B. Policy Development

PGS policy should develop in two steps. The agency should first examine the four policy goals described above to identify areas of overlapping interest among the potential stakeholders – what policy goals would benefit all or most of them? Addressing those needs should be the initial mission of the regulatory entity. Next, the agency should consider the areas where the policy goals conflict with one another. It should develop a regulatory framework that balances the interests in accordance with their level of priority.

1. Aligning Similar Interests

Governmental initiatives that benefit all or most stakeholders should form the fundamental features of a new regulatory policy. Achieving the following goals would improve the practice of ART for everyone: 1) ensuring the safety and efficacy of all services provided; 2) improving access to information regarding the risks and benefits of ART; and 3) providing increased analysis of

295. See, e.g., Spar, *supra* note 57, at 214-16.

296. See, e.g., Simpson, Rebar & Carson, *supra* note 203, at 1658-59.

297. See *Id.* at 1656.

298. See Adamson, *supra* note 213, at 941.

299. *Id.*

the impact of ART, and especially PGS, on both individuals and society.

The agency's first objective should be to develop procedural regulations to ensure the safety and efficacy of all procedures performed in ART clinics, as well as the reliability of the genetic tests used in conjunction with PGS. The United Kingdom's Human Fertilisation and Embryology Authority (HFEA) provides an excellent licensing model that could be modified for implementation in the United States to ensure the quality of both ART procedures and genetic tests.³⁰⁰ Under the U.K. licensing approach, clinics must be licensed to engage in any activity that involves the ex vivo creation of a human embryo, the storage of embryos and gametes, or research involving embryos.³⁰¹

By requiring each clinic that offers ART services to obtain and maintain a license to practice, the agency could require all clinics to have appropriately trained staff and maintain quality assurance standards. In addition, by licensing the clinics, the agency could ensure that all clinics reported practice and outcome information to a central database for analysis of child and maternal health risks. The licensing approach would also grant the agency the ability to sanction clinics that do not comply by suspension or revocation of their license.

This licensing approach can be broadened to include laboratories that provide genetic tests for PGS. PGS procedures require a degree of expertise and skill beyond that of a typical diagnostic testing laboratory,³⁰² given that it requires testing on a single biopsied cell within a short window of time. Laboratories that provide these services should also receive licenses that demonstrate staff qualifications, procedures to avoid misdiagnoses or embryo mix-ups, and the reliability of their tests. In addition, the agency should create procedural standards for gene variations that may be identified through PGS, based on the reliability of available genetic tests, the variation's contribution to the particular disorder (alone or in combination with other identifiable genes), and each variation's penetrance.

The agency's second objective should be to increase understanding of PGS practice. Any policy approach should include provisions to sponsor additional research on ART, create an ART central database to gather and analyze information, and disseminate information to patients, physicians, and the public regarding the uses of PGS.

300. See also FUKUYAMA, *supra* note 198, at 203-04; Fahrenkrog, *supra* note 20, at 779; Parens & Knowles, *supra* note 20, at S18-21; cf. PRESIDENT'S COUNCIL, *supra* note 112, at 220-24.

301. Human Fertilisation and Embryology Act. 1990, c. 37, § 5 (U.K.); see also Margaret Foster Riley with Richard A. Merrill, *Regulating Reproductive Genetics: A Review of American Bioethics Commissions and Comparison to the British Human Fertilisation and Embryology Authority*, 6 COLUM. SCI. & TECH. L. REV. 1 *passim* (2005) (providing a detailed description of the licensing process).

302. GENETICS & PUB. POLICY CTR., *supra* note 127.

The agency should establish key research objectives and provide funding to address the unanswered questions regarding PGS use. For instance, studies should be done to determine whether embryo biopsy harms embryo development or affects the long-term health of children.³⁰³ The government should also sponsor research on public sentiment regarding the appropriate uses of PGS and the likely demand for genetic tests.

Since PGS practice will continue while this research is being performed, the government should create a central database of information on IVF and PGS procedures. ART clinics should be required to submit information on all IVF and PGS procedures performed, including the following: the medical history of the couple; the procedures used to create the embryo; the number of embryos created and transferred; the implantation, pregnancy, and live birth success rates; the health outcomes of all women; the immediate health outcomes of all babies born via the procedure; all genetic tests performed; and embryo selections made. ART clinicians should ask all parents at the time of ART treatment initiation to consent for this information to be reported to the federal government and used for research. In addition, parents and children born through ART procedures, upon reaching the age of assent, should be asked to consent to having the child's health status reported to the federal database on an annual basis for monitoring and research. Pediatricians could simply forward check-up information to the database stripped of all identifying information and in compliance with all federal privacy requirements.³⁰⁴ The database could expedite identification of risks to children and women and could ensure that physicians and patients make reproductive decisions on the best information available.

Although additional information on the outcomes of ART and PGS procedures will provide benefit, ART providers are likely to resist the imposition of a mandatory reporting requirement in addition to FSCRCA. FSCRCA's reporting requirements should form the foundation of the central database and be broadened to include additional information related to PGS. Maintenance of FSCRCA's reporting requirements should be transferred from the CDC to the new regulatory body. Providing proper funding to establish the database and assist practitioners in meeting the reporting requirements should also alleviate some of their resistance.³⁰⁵

303. Federally sponsored research on whether embryo biopsy impedes embryo development will most likely violate the Dickey-Wicker Amendment. *See* Balanced Budget Repayment Act of 1996, Pub. L. No. 104-99 § 128, 110 Stat. 26, 34. This amendment should be repealed to permit research on the effectiveness of ART to proceed. Research on the long-term health outcomes of children born via PGS will be less likely to violate the amendment, as the research could start from their birth.

304. *See* 45 C.F.R. § 164.501 (2007).

305. *See* Simpson, Rebar & Carson, *supra* note 203, at 1658.

The government should also create educational materials detailing the risks, benefits and alternatives to IVF and PGS for distribution to physicians, patients and the public. Stimulating public debate will be essential to creating effective policy regulations for PGS use.

The third policy goal should be to improve analysis of PGS's effect on both individuals and society. Monitoring the demand for certain genetic tests reported in the PGS central database will be essential for understanding the potential social risks associated with PGS use. Policymakers should combine this data with information from public discussion and surveys to determine whether access barriers to PGS affect health disparities or whether individuals use PGS in ways that reinforce discrimination.

2. Balancing Conflicting Interests

The most significant challenges of regulating PGS will arise when the interests of the various stakeholders conflict. Conflicts are most likely to occur when prospective parents want to use PGS in ways that threaten harm to a child or society. The government must develop a strategy for handling these conflicts. Examining policy approaches taken by other countries provides insight for developing U.S. policy.

Other countries have taken a range of approaches to minimize the risk of harm from PGS. Banning the procedure altogether, as Germany, Austria, Switzerland, and, more recently, Italy have done, is overly restrictive given the speculative nature of social harms arising from PGS.³⁰⁶ However, other approaches warrant further consideration. Countries in which PGS occurs have generally selected two regulatory features: a serious impairment requirement and an indication analysis. The severe impairment requirement restricts the use of PGD to testing only those genetic or chromosomal disorders that would cause severe impairment. Under the indications analysis approach, an agency reviews each indication on a case-by-case basis and determines which uses are appropriate.

While both of these approaches offer improvements over the United States' current laissez faire system of ART regulation, neither approach is well suited to our political system or to address recent advances in PGS technology. The severe impairment requirement, a highly precautionary approach, impinges significantly upon reproductive liberty in the absence of substantiated risk. The indications analysis approach requires an excessive amount of oversight and monitoring and favors precaution over reproductive freedom. In the absence of substantiated risk of harm, restricting the use of reproductive technologies may run afoul of constitutionally protected reproductive liberties. Likewise, such an approach will

306. See *supra* notes 171-174 and accompanying text.

likely receive significant resistance from both physicians and patients. A more politically feasible and less-disruptive regulatory model would establish safety and efficacy regulations, monitor the use of ART practice, and then be prepared to intervene if and when risks appear on the horizon. This approach offers significantly more protection than the current lack of regulation, without unnecessarily stifling the development and use of recent advances in ART.

a. Severe Impairment Requirement

Nearly all forms of regulation regarding PGS require that the risk of the condition or disorder tested for be sufficiently grave.³⁰⁷ Most countries and professional societies that allow PGS limit genetic testing of embryos to only those conditions that will result in serious or severe impairment. For instance, the Netherlands restricts PGS use to “serious conditions.”³⁰⁸ In such countries, the only goal of PGS is to bring about the birth of a healthy child.³⁰⁹ Some regulatory bodies have gone further to restrict PGS to only those conditions for which medicine cannot provide a remedy; for example, the Australian Medical Association recommends PGD testing only when the disease is permanent.³¹⁰ For the most part, governments and professional societies have left the decision of what qualifies as a “serious” or “severe” condition to the patient and the physician.³¹¹

The definition of “severe impairment” largely determines the scope of the

307. Knoppers & Isasi, *supra* note 172, at 2696. Examples of countries with a severe or serious impairment requirement include the United Kingdom, Japan, India, France, and the Netherlands. *Id.* at 2697.

308. See Health Council of the Neth. *Pre-implantation Genetic Diagnosis*, in REPORTS 2006: EXECUTIVE SUMMARIES 9, 9 (2006), available at <http://www.gezondheidsraad.nl/pdf.php?ID=1646&p=1>.

309. See Knoppers & Isasi, *supra* note 172, at 2696-97 (describing policies in the Netherlands, France, Japan, the United Kingdom, and Australia) (citing Law No. 94-654, art. R2131-7 (1994) (Fr.); HUM. FERTILISATION & EMBRYOLOGY AUTH., CODE OF PRACTICE (5th ed. 2001); Act Containing Rules Relating to the Use of Gametes and Embryos [The Embryos Act], Stb. 2002, 338 (Neth.), available at http://www.minvws.nl/includes/dl/openbestand.asp?File=/images/engembryowetstekst_tcm20-107819.pdf; JAPAN SOC'Y FOR HUMAN GENETICS ET AL., GUIDELINES FOR GENETIC TESTING (English ed. 2004), available at http://jshg.jp/pdf/10academies_e.pdf). Permitted indications tends to include the screening for X-linked disorders, autosomal recessive disorders (such as cystic fibrosis, Tay-Sachs, and spinal muscular atrophy), autosomal dominant disorders (such as myotonic dystrophy and achondroplasia), and chromosomal abnormalities. See, e.g., JAPAN SOC'Y FOR HUM. GENETICS ET AL., *supra*, at 7.

310. AUSTRALIAN MED. ASS'N, HUMAN GENETIC ISSUES 3 (2002), available at [http://www.ama.com.au/web.nsf/doc/SHED5G7DBE/\\$file/healths_gd_ps_human%20genetics%20issues.pdf](http://www.ama.com.au/web.nsf/doc/SHED5G7DBE/$file/healths_gd_ps_human%20genetics%20issues.pdf).

311. See Knoppers & Isasi, *supra* note 172, at 2699.

regulation, but identifying those disorders that cause a “severe impairment” is extremely difficult. In fact, ART practitioners Joe Leigh Simpson and colleagues have argued that “[c]odifying diseases for which PG[S] should or should not be allowed is hopelessly naïve”³¹² Does severe impairment imply that a disorder shortens the life span of the individual? Must the disorder be incurable? What if the gene only confers a small probability of a very severe disorder? Should the disorder qualify the individual for disability benefits, such that one or more major life activities are limited? What if it does not present until later in life, but has very severe symptoms, like Huntington’s disease or Alzheimer’s disease?

If defined narrowly to only include those disorders that result in severe suffering and death at an early age, PGS use will continue to have a minimal impact. This approach would permit physicians to provide PGS only in cases where the benefit obtained by parents in selecting against a disease or disorder substantially outweighs any risks. As a result, fewer offspring would be born from the procedure.

Under this narrow definition, the social impacts of PGS would be limited as well. PGS for serious disorders would most likely be covered by insurance, such that lack of financial access to care will not significantly exacerbate health inequities, except between the insured and uninsured. A narrowly defined severe impairment requirement would also limit discrimination, as only a small population would have access to the procedure and a smaller population would be living with the disorders.

A more broadly defined severe impairment requirement that included, for example, disabilities such as blindness and deafness, might expand the potential for certain social harms associated with PGS. Compared to the narrow serious impairment approach, increased numbers of individuals would already live with disorders identifiable by PGS. This could increase discrimination against individuals living with the disorders and create greater disparities in use.³¹³

The severe impairment requirement is under-inclusive. Preventing individuals from selecting for traits that do not confer a severe impairment is not warranted by risks to either the offspring or society. While being born through IVF and PGS increases the risk that a child will have a serious health complication, the overall risk remains relatively low.³¹⁴ While these risks should be significant enough to outweigh the benefit of selecting for many non-medical

312. Simpson, Rebar & Carson, *supra* note 203, at 1658.

313. Discrimination could increase in two ways. First, by offering a way for parents to avoid having a child with a specific disorder, PGS serves to increase discrimination against those with the disorder, especially if only wealthier people have access. Secondly, by screening for a wider range of conditions, more people will be exposed to discrimination.

314. See generally *supra* note 15.

traits, there is not sufficient evidence of harm to offspring or society at this time to warrant restriction of PGS use to only the most severe disorders.

The ability to select for non-severe traits in addition to a severe trait will further undermine the logic of the severe impairment requirement. For couples who have met the initial clinical indication requirement to undergo PGS, such that the benefits of screening for a certain condition already outweigh the risks, screening their embryos for additional genetic variations presents no additional risk to the offspring or the mother. As a result, a severe impairment requirement would prevent parents from accessing additional information, medical or non-medical, about their embryos for non-serious conditions. In this scenario, the only justifiable arguments against permitting the parents from screening for additional conditions are that such screening will result in social harm.

Social concerns that may justify the severe impairment requirement approach arise largely from the potential for discrimination and respect for the embryo. As noted above, many countries limit PGS use to only severe conditions to limit the extent of eugenic practices and discrimination.³¹⁵ However, this approach is overly broad as an effort to protect society from discriminatory practices. Many alleles that are not associated with serious impairment do not raise concerns about discrimination. For instance, parents selecting an embryo that is a tissue match to a sick sibling, an entirely non-disease related trait, would not constitute discrimination against individuals with other tissue types. Consider also screening against alleles associated with a common but not severe allergy, such as an allergy to cats. Permitting parents to select embryos on this basis would benefit cat-loving parents, while not harming other members of society. In this regard, the severe impairment approach appears overly rigid without being substantiated by viable risks.

In sum, the severe impairment requirement has numerous drawbacks. By restricting the conditions for which PGS can be used, the severe impairment requirement unnecessarily constrains parental autonomy in light of the known individual and social risks. The policy would require the government to define those disorders that qualify as “severe,” which would be extremely challenging. Such a policy approach also has the potential to increase discrimination against individuals with the listed disorders. To avoid these concerns, the government should err on the side of granting parents expansive autonomy to make choices, which should only be limited in cases of substantiated harms to others.

b. Indications Analysis Approach

Another possible approach would be to examine each indication, or specific reason for conducting PGS, on a case-by-case basis to determine the risks to

315. Knoppers & Isasi, *supra* note 172, at 2697.

individuals and society.³¹⁶ A few legal and ethical scholars have suggested that the United States model its ART regulations after the indications approach taken by the United Kingdom's HFEA.³¹⁷ Most notably, Lori Knowles and Erik Parens suggest the creation of a Federal Reprogenetics Technologies Board,³¹⁸ and Frances Fukuyama and Franco Furger recommend the creation of an independent federal agency to address human biotechnologies and ART.³¹⁹ While the creation of an independent federal agency to regulate the practice of ART is the best strategy, the HFEA indications approach has significant flaws that leave it unprepared for the future challenges of PGS.

Under the U.K. indications approach, clinics are prohibited from engaging in any activity that involves the ex vivo creation of a human embryo, the storage of embryos and gametes, or research involving embryos, except as permitted by an HFEA license.³²⁰ ART clinics must receive a license approving the use of IVF and PGS as "treatment services."³²¹ Licenses are narrowly tailored to specific indications. In order to provide PGD, the HFEA Code of Practice requires clinics to submit a new application for every new PGD indication it wishes to provide and for every new genetic test or combination of tests they want to use.³²²

The indications approach has significant benefits. The HFEA is dexterous at responding to scientific developments that affect ART research and practice.³²³ The regulatory infrastructure enables the authority not only to evaluate the social, ethical, and scientific implications of a particular indication, but it also allows the authority to react quickly and effectively to changes in information by issuing licenses or suspending them. The indications approach also permits clinics to evaluate couples on the full extent of their personal situation, rather than evaluating uses only.³²⁴

By combining comprehensive monitoring and indication licensing, the indications-based approach offers a complete examination of all of the risks to offspring. By keeping records of each child born via PGS, the HFEA can rapidly identify any adverse health outcomes associated with the procedure. The agency can easily incorporate new risk information into existing practice by initiating

316. For instance, sex selection for family balancing and sex selection to avoid an X-linked disorder would use the same test for different indications.

317. FUKUYAMA & FURGER, *supra* note 20, at 14-23; Fahrenkrog, *supra* note 20, at 779; Parens & Knowles, *supra* note 20, at S18-21. The HFEA examines each indication for conducting PGS.

318. Parens & Knowles, *supra* note 20, at S18-21.

319. FUKUYAMA & FURGER, *supra* note 20, at 14-23.

320. Human Fertilisation and Embryology Act, 1990, c. 37, § 5 (U.K.).

321. *Id.* at § 3.

322. HUMAN FERTILISATION & EMBRYOLOGY AUTH., CODE OF PRACTICE pt. A.13.8-9 (7th ed. 2007), available at <http://cop.hfea.gov.uk/cop/pdf/COPv2.pdf>.

323. Riley & Merrill, *supra* note 301, at 58.

324. *See Id.* at 57-58.

investigations,³²⁵ considering new data during the licensing process or modifying existing licenses. Because the HFEA examines each PGS indication, the risks and benefits can be weighed in the most accurate manner possible. Overall, a licensing approach permits PGS use to expand as genetic testing and reproductive technology improves, but in a controlled manner.

Examining PGS uses on a case-by-case basis also provides a thorough method for identifying and considering social impact. An independent regulatory body like the HFEA would have the ability to consider the social impact of permitting an individual indication of PGS, while monitoring the numbers of individuals undergoing PGS for a specific purpose to determine if a broader social effect may occur. Only by overseeing usage and keeping in touch with public sentiment could a society adequately attempt to weigh important social interests, minimize health disparities, eliminate discrimination, and define the appropriate treatment of embryos.

However, as practiced by the HFEA, the indications approach also requires more government intervention than the risks of PGS practice currently warrant. Requiring a committee to evaluate and license each clinic for each potential use or combination of uses is overly burdensome, expensive, and time-consuming. As the number of genetic tests expands and PGS testing for multiple traits becomes available, licensing each clinic to use each specific indication will be impossible. UK clinicians have argued that licensing each use interferes with the doctor-patient relationship and patient privacy.³²⁶ Others complain that the licensing system creates unnecessary delays for time-sensitive treatments and further delays the already limited access to treatments available to underserved populations.³²⁷

The United States could choose a modified approach that requires agency approval each time a new genetic test was provided for PGS. While this would greatly reduce the time and expense required for PGS licensing, microarray PGS testing would quickly negate the efficacy of such an approach. For instance, the agency might prohibit PGS solely for non-medical sex selection on the basis that the benefit of selecting for a girl does not outweigh the risks that the child will incur during the procedure. For a couple undergoing PGS to screen for a severe disorder, denying the license for broad non-medical sex selection would eliminate the opportunity to select girls from the remaining healthy embryos, even though this selection would pose no risk to the offspring. Any use of PGS that the agency could deny solely based on risk to the children from the PGS procedure could become permissible if paired with screening for a more severe genetic condition that would outweigh this risk.

325. *Id.* at 58.

326. *Id.* at 24.

327. *Id.*

The government could attempt to license those uses that qualify as “clinically indicated,” such that the benefits of engaging in PGS outweigh the risks, so that other tests, like non-medical sex selection, could be licensed for use only in combination with a clinically indicated use. Advances in PGS could also confound this approach, as the benefit of screening for numerous genetic conditions at once may outweigh the risks to the offspring of conducting PGS, even if no singular test on its own would warrant the use of PGS. In the absence of demonstrated individual or social risk from sex selection, prohibiting it in all cases would fail to give sufficient weight to parental autonomy.

In light of these challenges, the government should not seek to evaluate each individual use or combination of uses, as this approach would be extremely burdensome and unlikely to produce the desired effect. Instead, the government should attempt to establish an infrastructure that enables it to monitor PGS use for potential risks to offspring and society, provide guidance on appropriate uses, and place restrictions on uses only when their harms clearly outweigh their benefits.

c. Balancing Framework

Given the political climate and constitutional freedoms in the United States, neither the indications framework nor the severe impairment requirement offers a viable policy option. To resolve conflicts of interest between protecting reproductive autonomy and protecting individuals and society from unjust harms associated with ART use, the United States should adopt a decisional framework based on the interests at stake and their relative importance. Following current practice and Mill’s principle the regulation of ART practice should originate from a position of parental autonomy and sanctity of the medical profession. Under this approach, individuals and their physicians would be able to decide whether to use ART procedures, including PGS, to screen for any condition without governmental approval. However, this right would not be absolute: their autonomy must be balanced against the government’s interest in protecting individuals and society.

Such a balancing approach would suggest the need for immediate governmental action, as well as monitoring to determine when future action is required. Currently, the agency should restrict those medical practices in which the clinical benefit is outweighed by the risk to the child. For instance, parents and physicians often opt to transfer more than one embryo to the uterus to improve the odds of pregnancy, but this practice also increases the health risk to each embryo transferred.³²⁸ In order to diminish the number of multiple births,

328. See Bonduelle et al., *supra* note 15, at 418; Hansen et al., *supra* note 97, at 729; Klemetti et al., *supra* note 14, at 1822; Soini et al., *supra* note 93, at 605-07.

the agency could decide to restrict the number of embryos transferred.³²⁹ The agency should also require clinics to maintain a strict code of medical ethics, such that PGS will only be provided when clinically indicated. The agency should provide practice guidelines to assist physicians in determining whether a specific procedure is clinically indicated, but the ultimate decision in any individual case should belong to both the physician and parents. Physicians are trained to make decisions regarding the risk-benefit ratio of a specific procedure and are better suited to make those decisions in individual circumstances. However, the government should require the clinics to report their use patterns, disclose success rates, and monitor clinic use patterns for repeat or egregious inappropriate uses. The government should also perform on-site inspections to ensure the accuracy of the reporting. In cases of abuse, the agency could suspend or revoke the license of the clinic.

In the future, the government should also reserve the right to restrict PGS use to select for certain alleles that would risk significant harm to society. For instance, if the practice of sex selection, on its own or as part of multi-use PGS, began to demonstrate significantly uneven selection patterns between males and females, as has occurred in China and India,³³⁰ the agency should prohibit PGS for non-medical sex selection. The agency might also have the ability to limit PGS use to demonstrate its respect for unborn human life even in the absence of individual or social risk.³³¹ The government's interest in protecting unborn life, which grows as the embryo matures,³³² would be quite limited at the preimplantation stage. But in some instances, the countervailing parental interest in selecting a specific gene variant may be minimal as well. The parental interest in selecting embryos based on non-medical characteristics of scant importance, such as eye color, may not outweigh the government's interest in demonstrating respect for the human embryo by not discarding it for a trivial purpose. In these situations, the government may wish to restrict certain uses of PGS in the absence of individual risk.

As genetic testing capabilities improve and the understanding of PGS risks develops, the challenges of balancing the respective interests will increase in size and magnitude. To mitigate the potential harms associated with unrestricted PGS use, Congress should develop the infrastructure necessary to address the current risks of PGS use as well as those visible on the horizon.

329. See Practice Comm., *supra* note 100, at S51-52.

330. See, e.g., Parliamentary Office of Sci. & Tech., *Sex Selection*, POSTNOTE 198, Aug. 2003, at 4, available at <http://www.parliament.uk/post/pn198.pdf>.

331. *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007).

332. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 869 (1992).

C. Assisted Reproductive Technology Authority

The preceding arguments suggest that Congress should create a national independent regulatory body, the Assisted Reproductive Technology Agency (ARTA), to perform five main functions: 1) establish a licensing system for ART clinics; 2) establish procedural guidelines and regulations for ART practice; 3) gather data on ART procedures, including PGS, long-term offspring and maternal health outcomes, and public sentiment; 4) monitor that data for individual and social risks; and 5) in the case that proven risks outweigh the benefits for certain procedures, regulate the use of PGS for certain indications using the novel balancing framework proposed above.

1. Procedural Regulations

ARTA's first responsibility will be to establish procedural requirements for ART clinics. All ART clinics should be required to obtain a license from ARTA. Licensing will signify that the clinic has met and continues to maintain certain minimum standards of safety, quality of care, and expertise. ARTA should require a license for clinicians who seek to perform highly technical procedures such as egg retrieval and embryo biopsy. Clinics should offer patients genetic counseling services by licensed genetic counselors. ARTA should also work with ASRM and SART to establish best practices guidelines for ART procedures. In addition to the laboratory regulations established by CLIA, ARTA should license genetic testing laboratories that perform tests for PGS.³³³ These laboratories should meet standards of accuracy, quality control, and quality assurance set by ARTA in order to obtain and maintain a license.

ARTA should then begin more long-term projects. First, the agency should create a database of information on all ART procedures occurring in licensed clinics. The CDC's requirements under FCSRCA should be turned over to ARTA and expanded to include additional information, including the number of embryos created, screened and transferred; the genetic and chromosomal analysis performed; implantation and pregnancy rates; multiple gestations, including information on reductions and live births; and infant health status. Parents should be asked to consent to providing their child's annual health status report to obtain health information from a representative sample of children born via PGS.³³⁴

333. If CMS eventually develops a genetic testing specialty and proficiency requirements that specifically address the quality of genetic tests for PGS, then ARTA could relinquish this responsibility to CMS.

334. Some parents may want to avoid having their children become permanent research subjects; however, since PGS has never been vetted through a randomized control trial for health outcomes, monitoring the children's health status is incredibly important. These health reports can be provided without significant burden to the parents or child via annual physician check-up reports

Women who undergo ART procedures should also be asked to provide updated reports of their health status at regular intervals. Due to the uncertainties associated with the current and future uses of PGS, more information is greatly needed to adequately regulate the procedure. By encouraging those who engage in PGS to provide information on their health outcomes, success rates, and reasons for using the technology, ARTA can effectively determine where government intervention is required. This would also enable ARTA to regulate without resorting to a precautionary approach that would require the agency to act before evidence of clear need. The license and monitoring approach of ARTA could provide a policy solution that lies between the United States' current laissez-faire approach and the precautionary tactics seen in many other nations that have either banned or heavily regulated PGS.³³⁵

ARTA should monitor the database to identify adverse health outcomes, the most common uses of PGS, possible discriminatory uses, and other issues of individual or social concern, including socio-economic and demographic use patterns. To maintain individual confidentiality, clinicians should remove all identifying data. As more non-disease-related genetic screening becomes available, ARTA should monitor the volume and popularity of such practices to determine if more rigorous standards of regulation are necessary.³³⁶ For non-disease related indications, ARTA should examine closely whether the risks and burdens of undergoing PGS to screen out the trait outweigh the potential benefit of selection.

ARTA should provide information to enhance the understanding of issues associated with reproductive genetics and PGS. It could work in collaboration with genetic counselors and clinic providers to develop educational tools to improve comprehension of the risks and benefits of PGS, as well as the alternatives available to prospective parents. ARTA should conduct research on the data collected in the database and make the data available to the public for independent research. In addition to promoting scholarly publications and research, ARTA should provide materials and programs to help laypersons understand the issues surrounding assisted reproduction and genetics. Efforts to educate and engage the public in conversation about ART and PGS will help ensure that policies created in this area reflect the needs and concerns of society as a whole, not just those with immediate financial or personal interests.

To determine the impact of certain indications, ARTA should work with a diverse array of individuals, including geneticists, pediatricians, members from the disability community, prospective parents, religious leaders, and others, to

until the child is eighteen, and then with the adult child's permission, on an every five-year basis after that. *See Soini et al., supra* note 93, at 611.

335. I am indebted to Amitai Aviram for this helpful description of the ARTA proposal.

336. PRESIDENT'S COUNCIL, *supra* note 112, at 197-98.

create PGS selection guidelines and decision analysis algorithms. This should be an ongoing project with public opportunities for input and transparency. These guidelines would be non-binding, but meant to assist clinicians and parents in determining whether undergoing PGS for a particular purpose or discarding embryos due to the presence of a specific allele is appropriate. ARTA's main role in establishing PGS selection guidelines would be to determine the social impact of various uses of PGS.

2. Substantive Regulations

In addition to creating and monitoring a database, establishing a licensing system, and developing practice and PGS selection guidelines, ARTA should establish a system for regulating the appropriate and inappropriate uses of PGS as they arise, as well as mechanisms to identify and address many of the social risks associated with PGS.

Initially, ARTA should permit parents and physicians to use PGS for any purpose for which they believe the benefits of the selection outweigh the risks to the offspring, mother, and society. The agency should create PGS selection guidelines to assist physicians in accounting for the benefit of selecting a child with a certain trait, the scientific accuracy of the genetic tests, the potential individual risks to the mother and offspring, the overall demand for the procedure, and the likely harm to others that might arise from its widespread use.

The first substantive standards ARTA should establish are those targeting the accuracy and reliability of genetic tests that may be used in PGS. Genetic tests for genes with low penetrance or low predictive value may be inappropriate for PGS. Likewise, the agency should establish minimum levels of association between the genetic loci tested for and the specific phenotype or physical characteristic of interest, and then require all genetic associations to be replicated with high reliability and without refutation before permitting the testing to be used in PGS.

To address potential social harms, ARTA should take steps to reduce the barriers to access for clinically indicated uses of ART for all members of society. ARTA should use information from the database to identify disparities in access as they arise and to determine factors contributing to the cause. The government could also seek to engage and inform the public about the available treatment choices and the risks and benefits that accompany them. If the barriers are financial, the governmental efforts could improve access to insurance coverage or provide subsidies for low-income families.³³⁷ In addition, any attempt to encourage individuals to select for or against any specific conditions may be

337. However, any attempts to do so should be weighed against other health priorities. Subsidies for ART may not become a priority for some time, if ever.

PREDICTING PROBABILITY

viewed as discriminatory or eugenic. With respect to PGS, efforts to reduce health disparities both in use of PGS itself or through selection for or against genetic conditions should be made solely with the goal of helping individuals obtain the necessary information and services to fulfill their health care goals. The government should neither encourage nor discourage the use of PGS in any particular group.

To address harms associated with discrimination, ARTA should examine whether the screening results in balanced or one-sided selection patterns, and whether those patterns reflect possible discrimination. For instance, concerns about sex selection in the United States have been tempered by the fact that prospective parents tend to select for boys and girls at similar rates. If parents began systematically selecting boys for non-medical reasons, especially if based upon discriminatory beliefs about the value of women, the government could pass regulation prohibiting this practice. Determining whether collective choices reflect discriminatory practices and at what point those choices create social harm will be one of ARTA's main tasks. Only through expert analysis of PGS use patterns and public sentiment could ARTA determine if such stigma and discrimination rose to the level of generating a social risk.

By putting a regulatory system in place to ensure the safety and efficacy of clinical practice and monitoring the use of PGS in the United States, we can gain many of the benefits associated with PGS, while preparing to identify and respond in a fast and efficient manner to any harms as they develop.

CONCLUSION

With little consideration for American preparedness, a technological revolution in reproduction is coming. Recent advances in DNA microarrays and bioinformatics will enable parents to select embryos based on a broad range of genetic information. While this information will offer prospective parents unprecedented decision-making capabilities regarding their future children, unregulated use of the technology poses significant risk to women, children, and society as a whole. To address these concerns, this Article advocates the creation of a novel regulatory system that establishes the middle ground between the current *laissez faire* approach and the precautionary approach taken in other countries. Under this system, the ARTA will provide both procedural and substantive regulation over the practice of assisted reproduction. Procedurally, ARTA should license all ART clinics and genetics laboratories that provide services for PGS, create a database of information on ART health outcomes and practice patterns, and monitor the database for risks to individuals and society. Substantively, the ARTA should establish a balancing framework that weighs various interests based on the priority and strength of the interest to determine whether certain ART practices should be regulated. Creating this infrastructure now will promote the safety of those individuals currently engaged in ART

practices, the informed choice of those seeking to use IVF and PGS in the future, and the ability of the United States to adapt appropriately as new challenges emerge.

Without question, passing any substantial legislation to establish a new regulatory entity will prove extremely challenging, especially laws that regulate reproductive practices. However, America's current lack of oversight and regulation over ART, and especially PGS, invites significant social change without pausing to consider what is at stake. While the proposal put forth in this Article may change during the regulatory process, I hope that it will contribute to the body of literature on the regulation of ART, stimulate further discussion of the implications of PGS, and serve as a sound beginning to the establishment of a regulatory framework for PGS.

One of the most challenging questions we face is how PGS use will impact the everyday lives of Americans. If widely used, PGS has the potential to dramatically change the way we reproduce, think about and relate to our children, perceive other members of society, and value pre-nascent human life. Without monitoring the use patterns of PGS and the public sentiment regarding current and future capabilities of the procedure, we have no way to predict the potential social impact of PGS. By pausing now to consider the future society we hope to create for our children, we will have a better chance of making it a reality.